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An Imperative for Action: Patients Are Waiting

Mary Woolley, President, Research!America

July 25, 2014

NIH Workshop on the Enrollment and Retention of Participants in NIH-funded Clinical Trials
Bethesda, MD

Overview of Presentation

- Key challenges
- What the public says about clinical trials: implications
- Recommendations for Action

"The current clinical trial paradigm is not sustainable."
—Dr. Janet Woodcock, Director, FDA Center for Drug Evaluation and Research

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Challenges We Can't Afford to Ignore

- Uncoordinated trial conduct—across federal agencies; across universities; globally
- Expensive, redundant data collection
- Incentives for researchers don't match patient need
- Incentives for physicians don't match patient need
- Failure to include patients every step of the way—from study design to report-out

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Media is Paying Attention

THE NEW YORKER

MEDICAL DISPATCH | JULY 21, 2014 ISSUE

ONE OF A KIND

What do you do if your child has a condition that is new to science?

BY SETH MNOOKIN

"Researchers … hesitate to share data with potential competitors, both to protect their funding and to insure that they get credit for their work … 'the current academic publication system does patients an enormous disservice.'"

—*The New Yorker*, July 21, 2014

"It isn't uncommon for studies to contradict each other, and there's no way for clinicians to know which one is right …"

—The *Washington Post*, April 15, 2014

The Washington Post

Health & Science

Scientists embark on unprecedented effort to connect millions of patient medical records

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Congress is Paying Attention

- 21st Century Cures Initiative (House E&C Committee)
  - Recent hearings all relevant to this workshop
    - Importance of the patient perspective
    - Data sharing/database creation—aid study recruitment
    - Administrative burden and IRBs
    - Patients as partners
    - Quantifying patient experience and attitudes
    - Personalized medicine
- Congressional Task Force on Biomedical Research & Innovation (Members of the House E&C and Appropriations)
  - Advisory Board appointed to provide advice & proposals on optimizing medical research pipeline, including clinical trial issues
- New Congressional Caucus formed on deadliest cancers
  - Inviting suggestions on raising patient enrollment and other challenges

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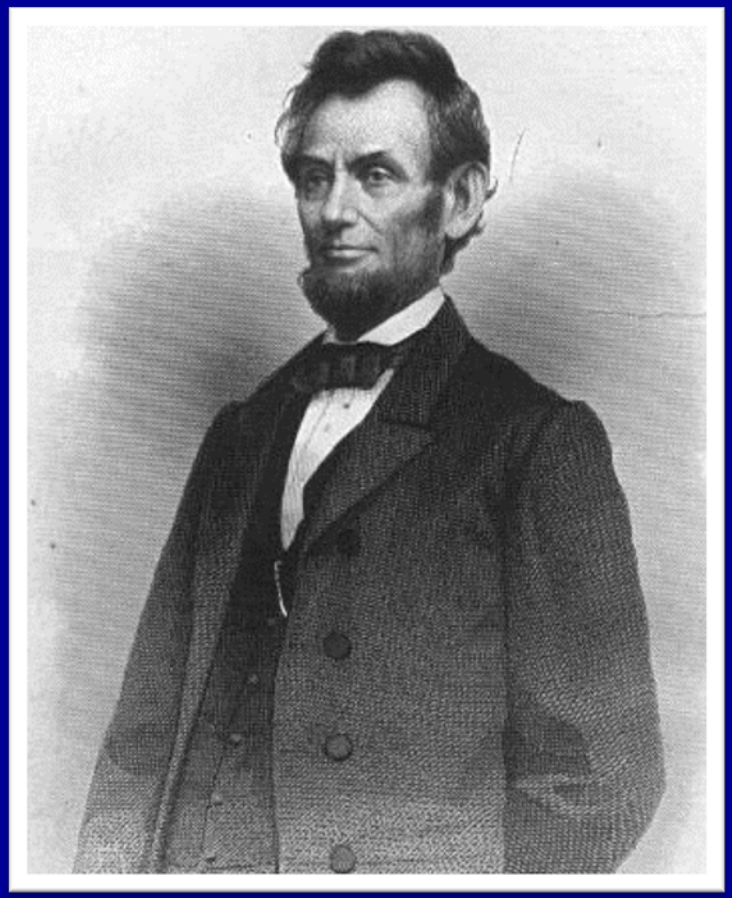
The Public is Paying Attention



"...public sentiment is everything. With public sentiment, nothing can fail; without it nothing can succeed."

President Abraham Lincoln

Poll Methodology – May 2013

General population poll plus four separate polls of minority populations commissioned by Research!America

- General survey: sample size, 1,006; margin of error, +/- 3.2%
- African-American: sample size, 403; margin of error, +/-5%
- Asian: sample size, 300; margin of error, +/- 5.7%
- Hispanic: sample size, 406; margin of error, +/- 5%
- Non-Hispanic White (drawn from general survey): sample size, 684; margin of error, +/- 3.8%

*Due to rounding, the total may not add to 100 on some slides.

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Top Line Messages

For most topics covered, no significant differences observed between general population and over-sampled populations

- Important differences observed:
  - Altruism is more likely a motivating factor in trial participation among minority groups than in general population
  - Minority groups are more likely to admire people who volunteer for clinical trials
  - Lack of trust remains an issue among minority groups, slightly greater than the general population
  - Minority populations, especially African-Americans, more likely to say people are enrolled in clinical trials without being told

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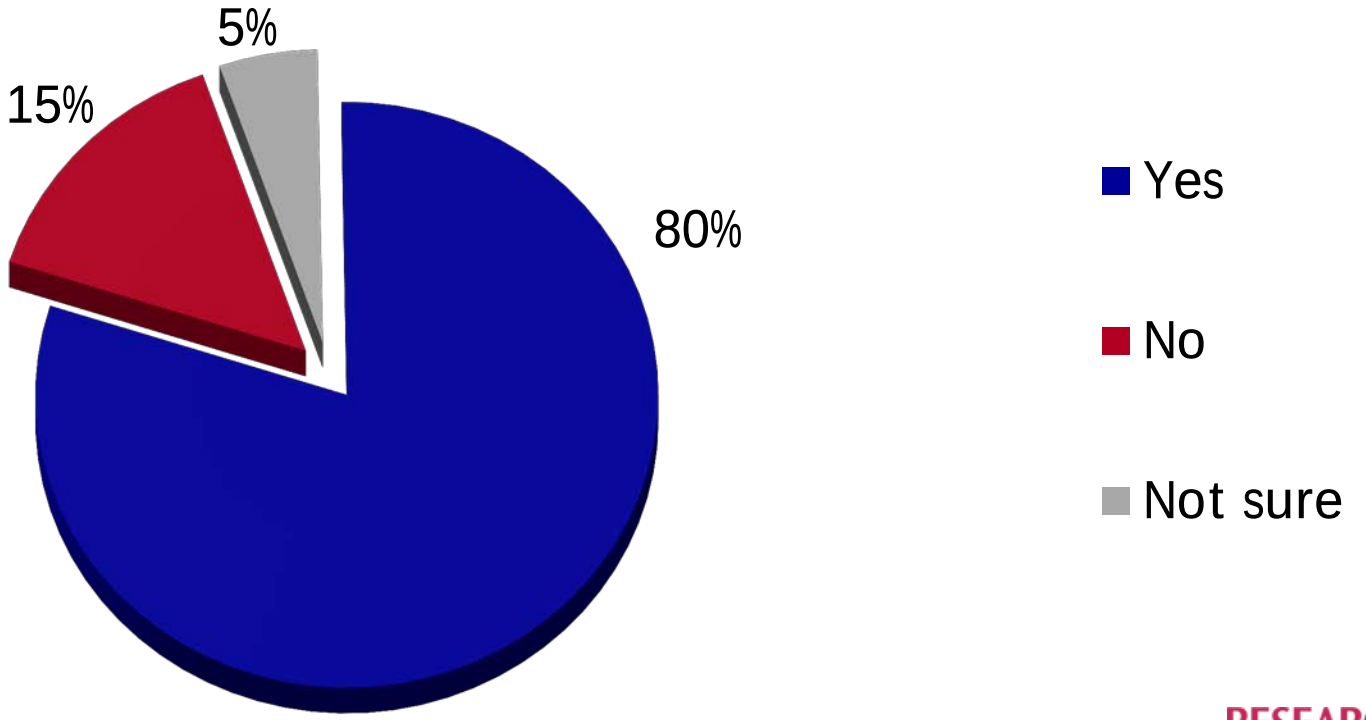
Patients Willing to Share Health Information for a Variety of Reasons

Please indicate your willingness to share your personal health information, assuming that appropriate privacy protections are in place.

Source: A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics in May 2013.

Wide Majority of Americans Have Heard of Clinical Trials

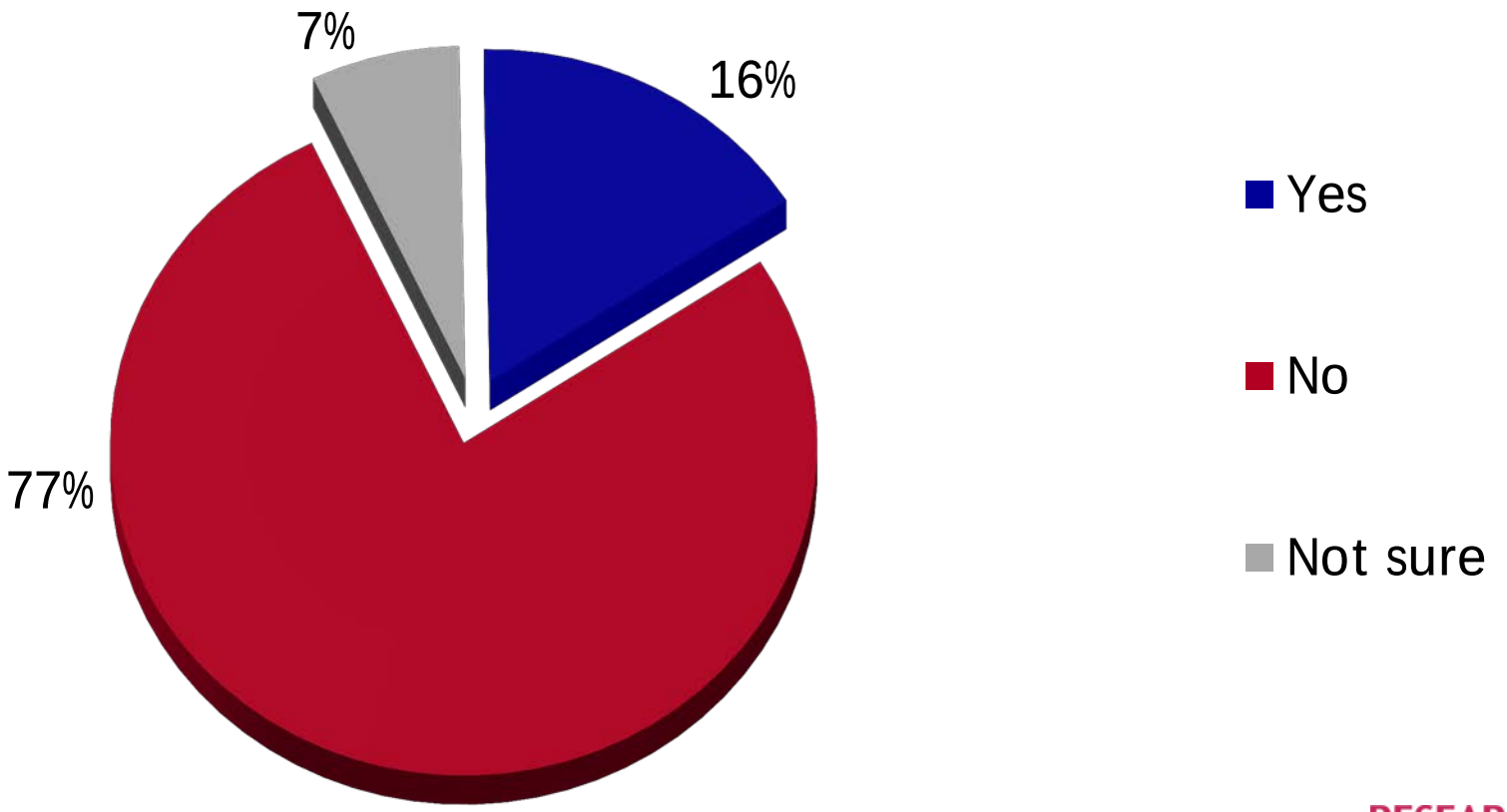
One kind of medical research is often referred to as a clinical trial. In this, volunteers choose to participate to test the safety and effectiveness of certain treatments, drugs or devices. Have you ever heard of a clinical trial?



Source: A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics in May 2013.

Wide Majority of Americans Have Not Participated in Trials

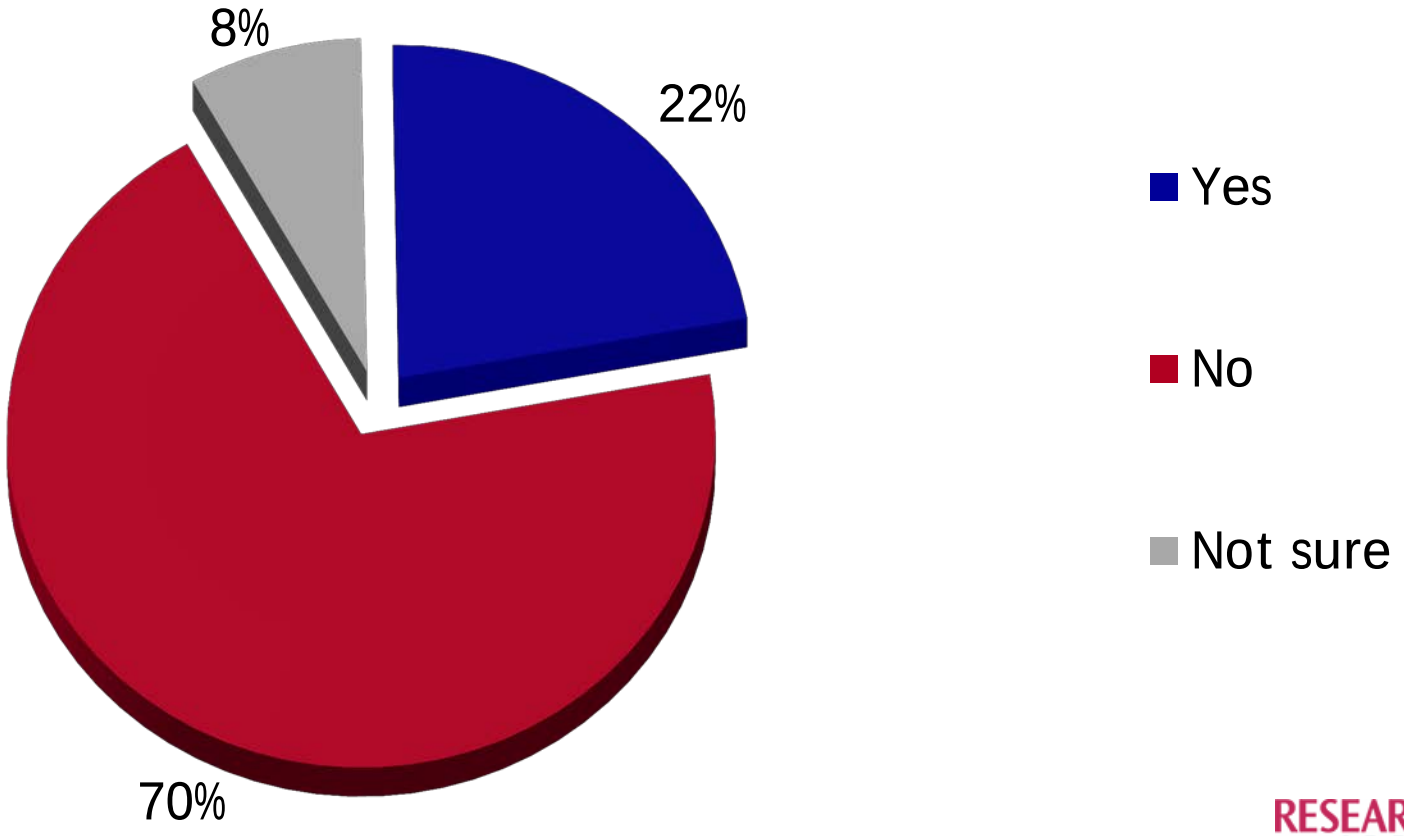
Have you or anyone in your family ever participated in clinical trials?



Source: A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics in May 2013.

Seven in 10 Say Practitioners Don't Talk About Medical Research

Has your doctor or other health care professional ever talked to you about medical research?



Source: A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics in May 2013.

Physicians, Internet are Primary Sources of Info on Clinical Trials

Where would you go to get information about clinical trials? (multiple responses allowed)

My doctor	60%
Online	57%
Hospitals	27%
Pharmaceutical companies	25%
Patient organizations	18%
Government institutions	16%
Foundations/charities	16%
Friends or family	14%
Other	>1%
Not sure	15%

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Source: A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics in May 2013.

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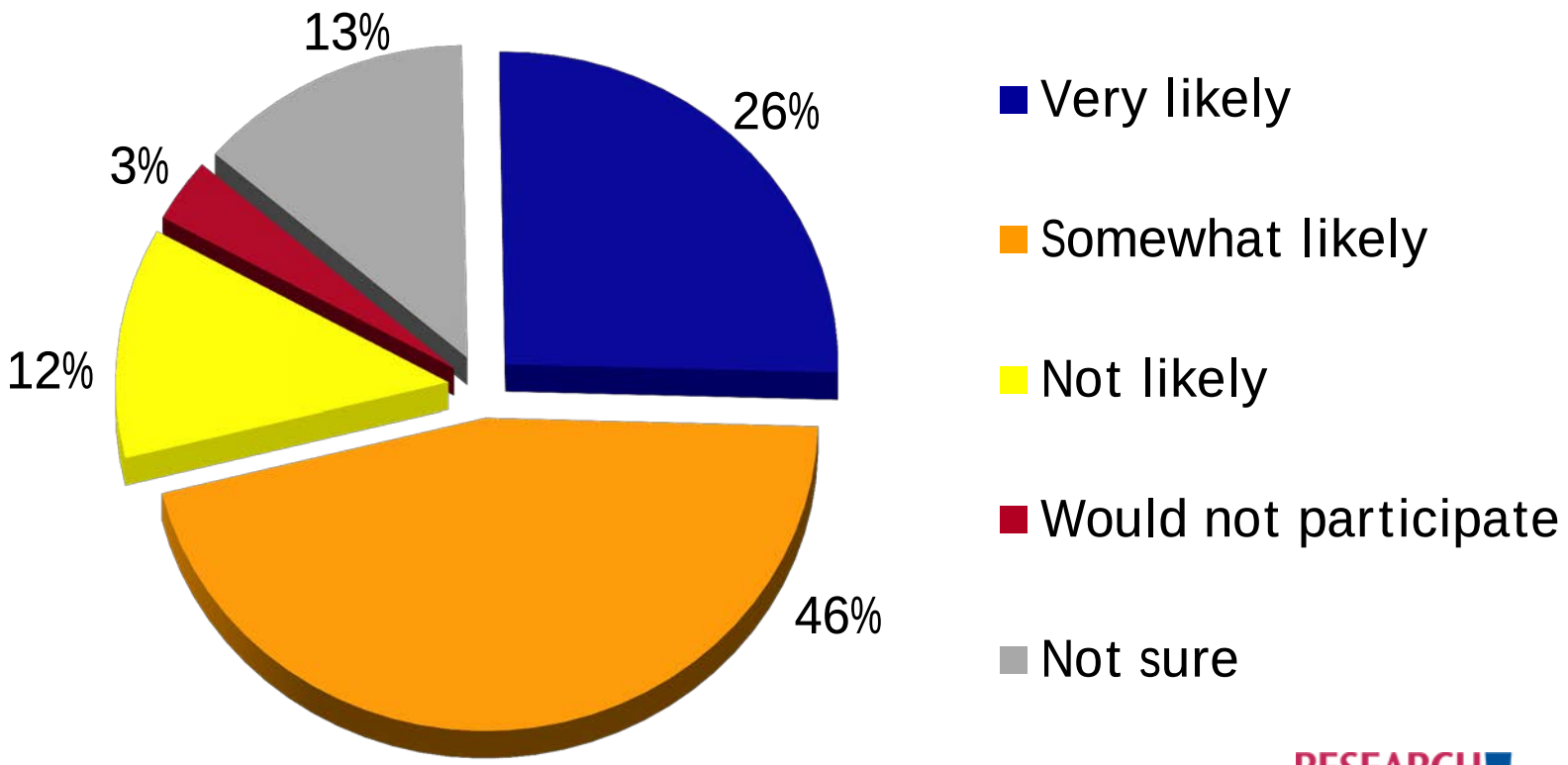
Physician Recommendations Matter to Potential Participants

If your doctor found a clinical trial for you and recommended you join, how likely would you be to participate in a clinical trial?



Source: A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics in May 2013.

Awareness, Trust, Risk are Barriers to Better Participation

Fewer than 10% of Americans participate in clinical trials. Which of the following do you think is a reason that individuals don't participate in clinical trials? (multiple responses allowed)

Not aware/lack of information	53%
Lack of trust	53%
Too risky	51%
Adverse health outcomes	44%
Little or no monetary compensation	35%
Privacy issues	27%
Too much time	27%
Not sure	11%

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Source: A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics in May 2013.

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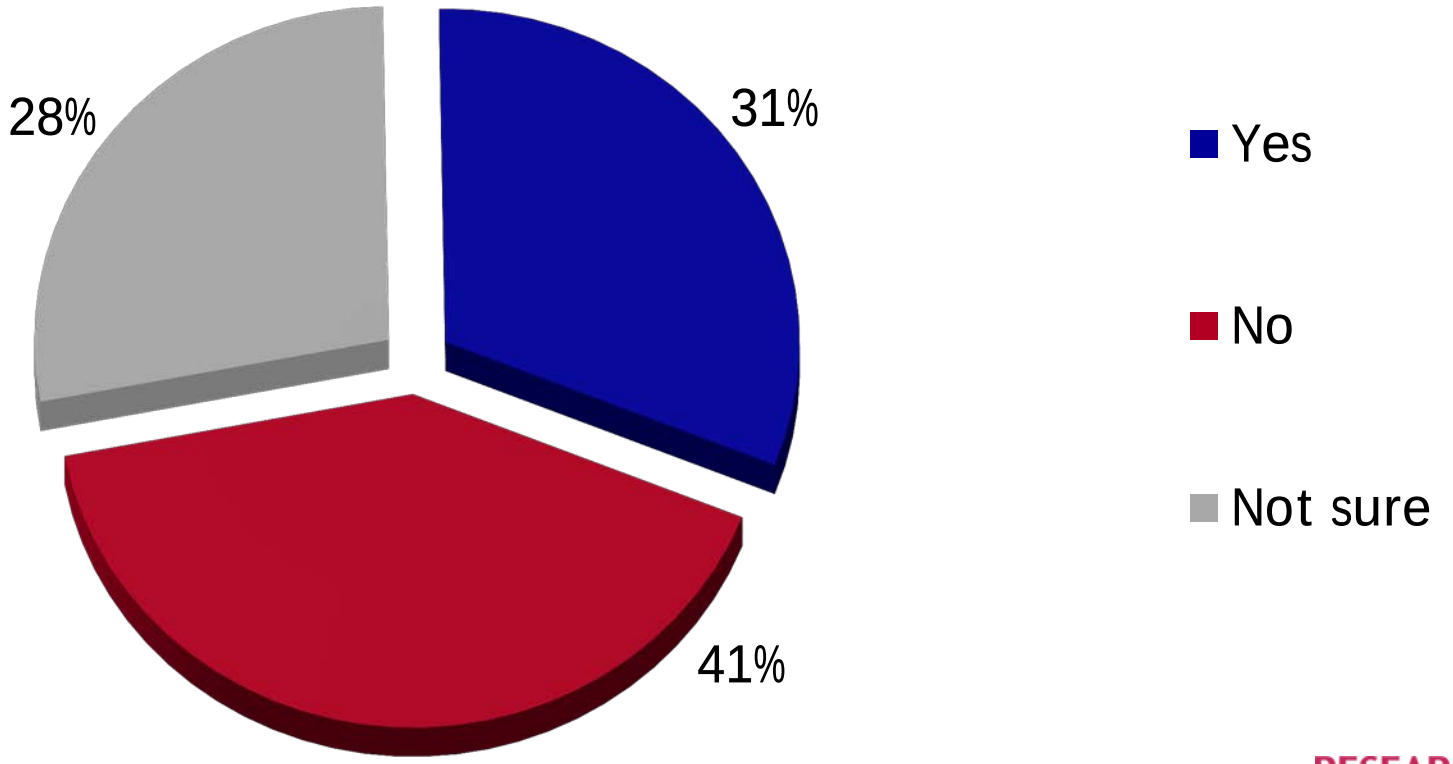
Opinions Split on Whether Patients are Enrolled Without Their Consent

Would you say that without being told, patients are sometimes included in clinical trials when they are receiving medical treatment?



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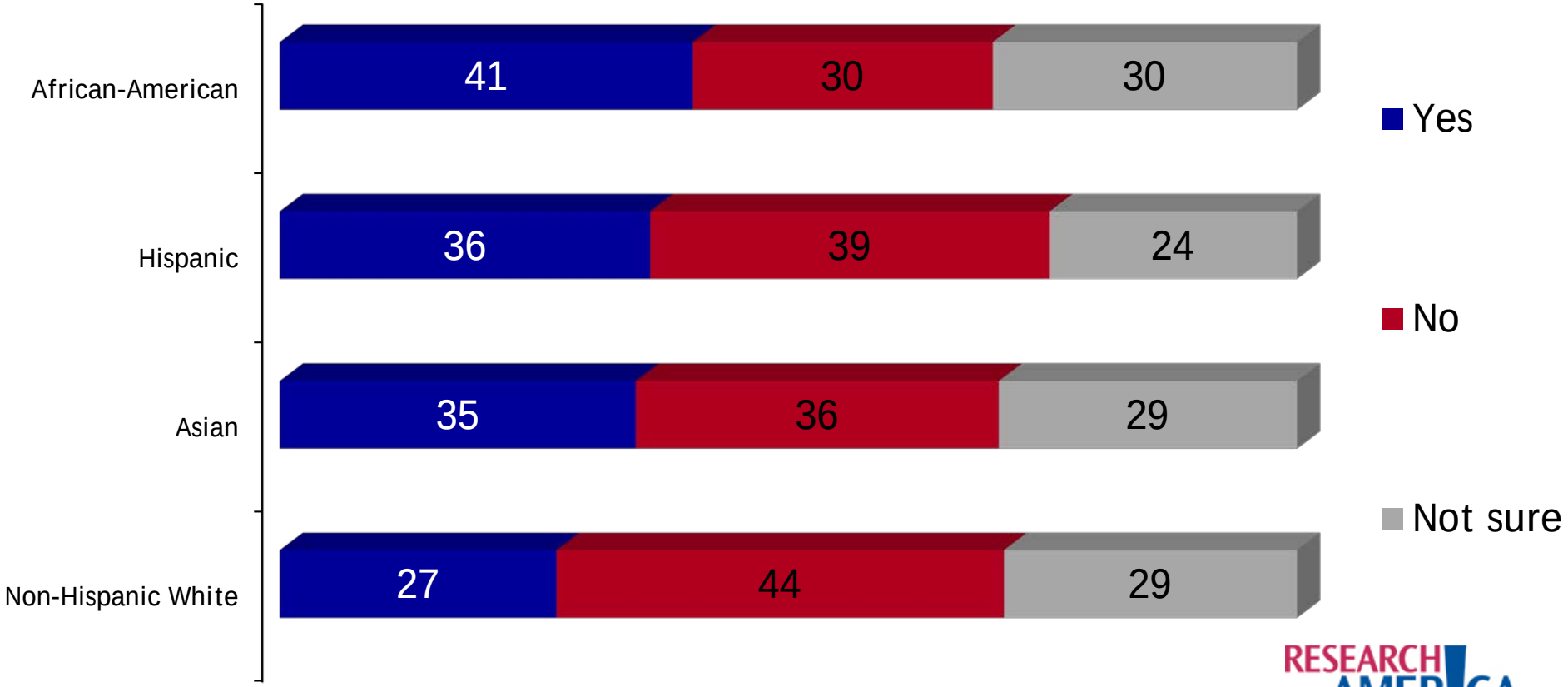
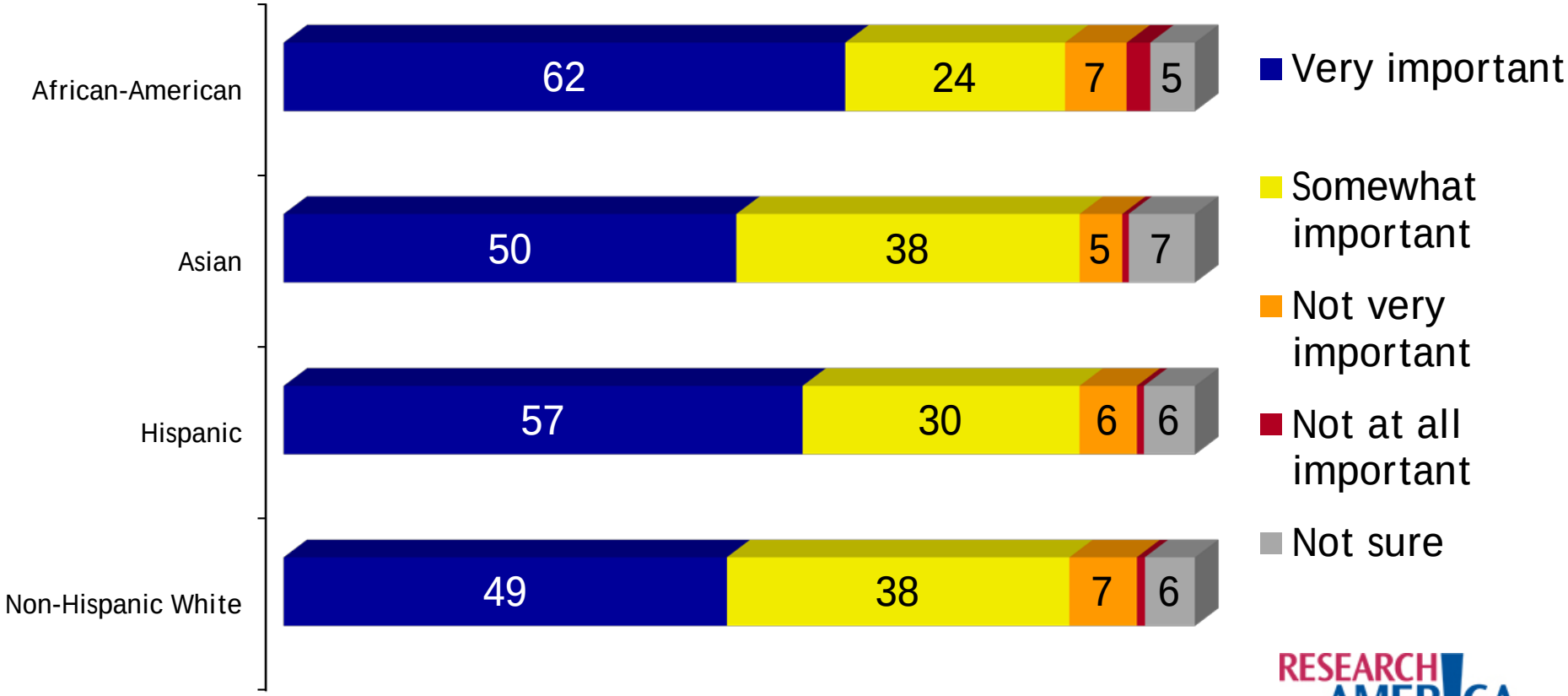


Source: A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics in May 2013.

Improving Others' Health Important for Participation

How important would the opportunity to improve the health of others be in your decision to participate as a volunteer in a clinical trial?



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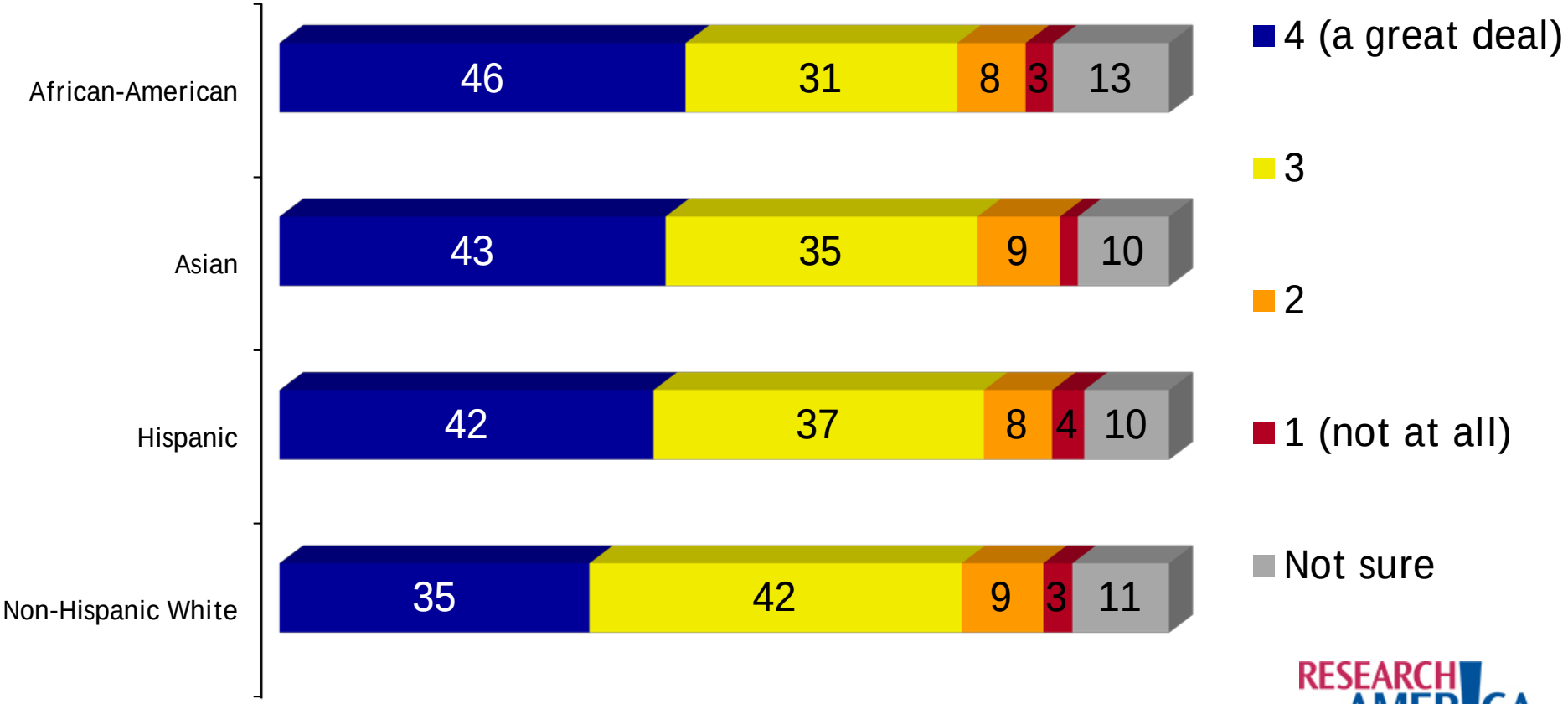
Americans Admire Clinical Trial Volunteers

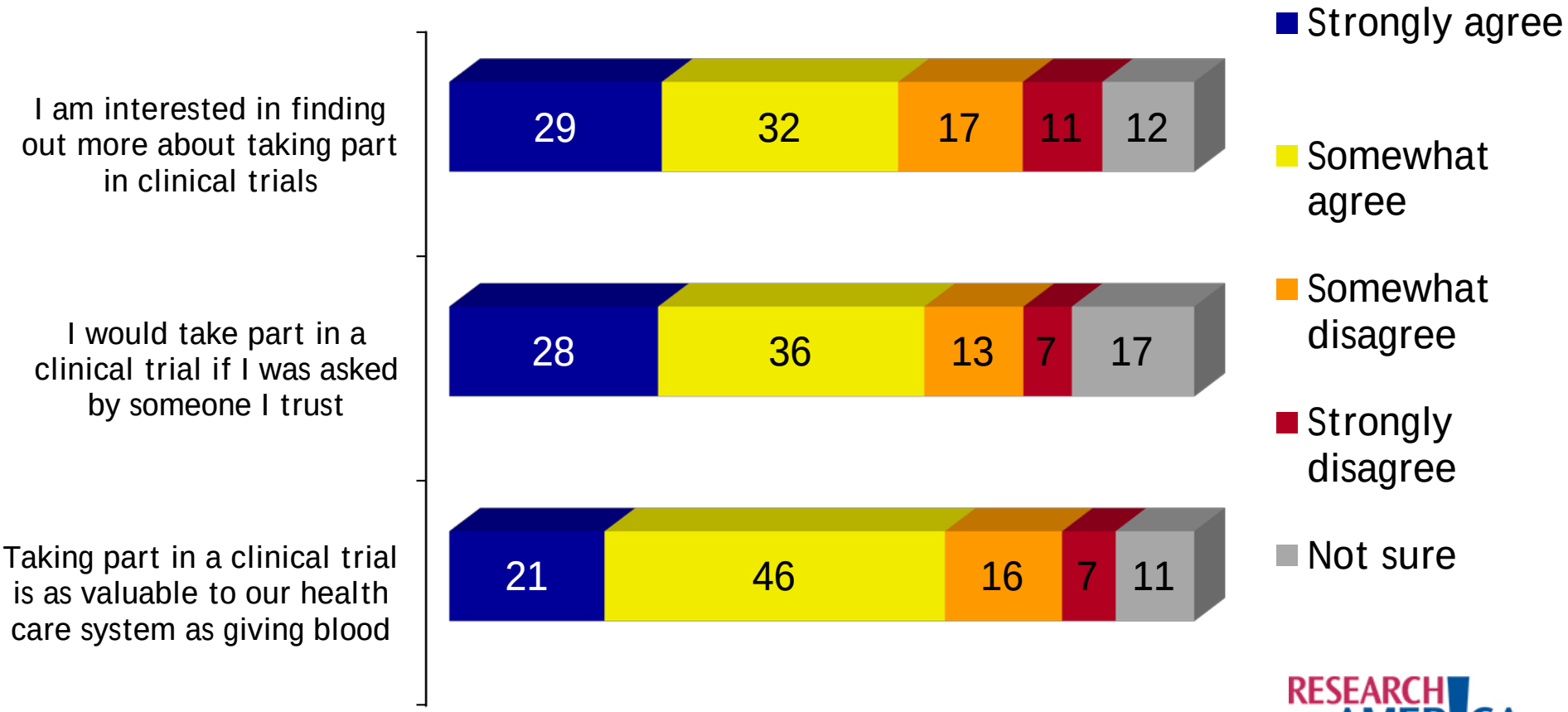
On a scale of 1 to 4, how much do you admire people who volunteer for clinical trials?



Source: A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics in May 2013.

Americans are Interested in Clinical Trials

Do you agree or disagree with each of following statements?



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Action Recommendations (1)

- Standardize and harmonize regulations: within US and globally
- End practice of every institution having unique consent form
- Learn from other nations, e.g. UK success in doubling cancer trial enrollment
- Share more data faster—across agencies, across the research ecosystem, with patients. PCORnet provides opportunity.
- Increase reimbursements to physicians for talking about research
- Use new technology and social media to improve two-way communication:
  - 'bring clinical trials to patients, instead of patients to clinical trials'
- Everyone involved in the conduct of research should look for opportunities to participate in research as a volunteer —experience can be a great teacher!

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Action Recommendations (2)

- Make volunteering for clinical trial participation as valued as organ and blood donation
- Use knowledge of concerns of special populations to do better study design and drive better enrollment and retention
- Engage patients every step of the way: "nothing about me without me"

"Gone are the days when we could just say, 'We're a cloistered community of researchers, and we alone know how to do this.'"
—geneticist Vandana Shashi,* The New Yorker, *July 21, 2014

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Remember the most important four words a researcher can say and convey:

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“I work for you.”

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