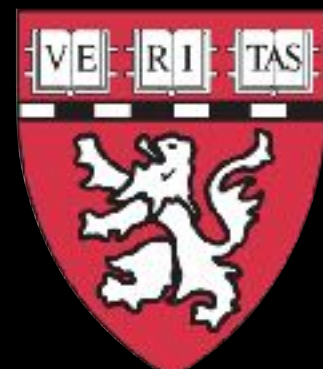


# Inequities in Clinical Research

How study teams can support Black participants



Jonathan Jackson, PhD  
Director, CARE Research Center  
November 7, 2018

# Disclosure of conflicts of interest

- Employed by Massachusetts General Hospital
- Supported by grants from
  - Massachusetts General Hospital
  - The Michael J. Fox Foundation
  - Alzheimer's Therapeutic Research Institute
- Paid consultant for
  - All of Us Precision Medicine Initiative

# Goals for this talk

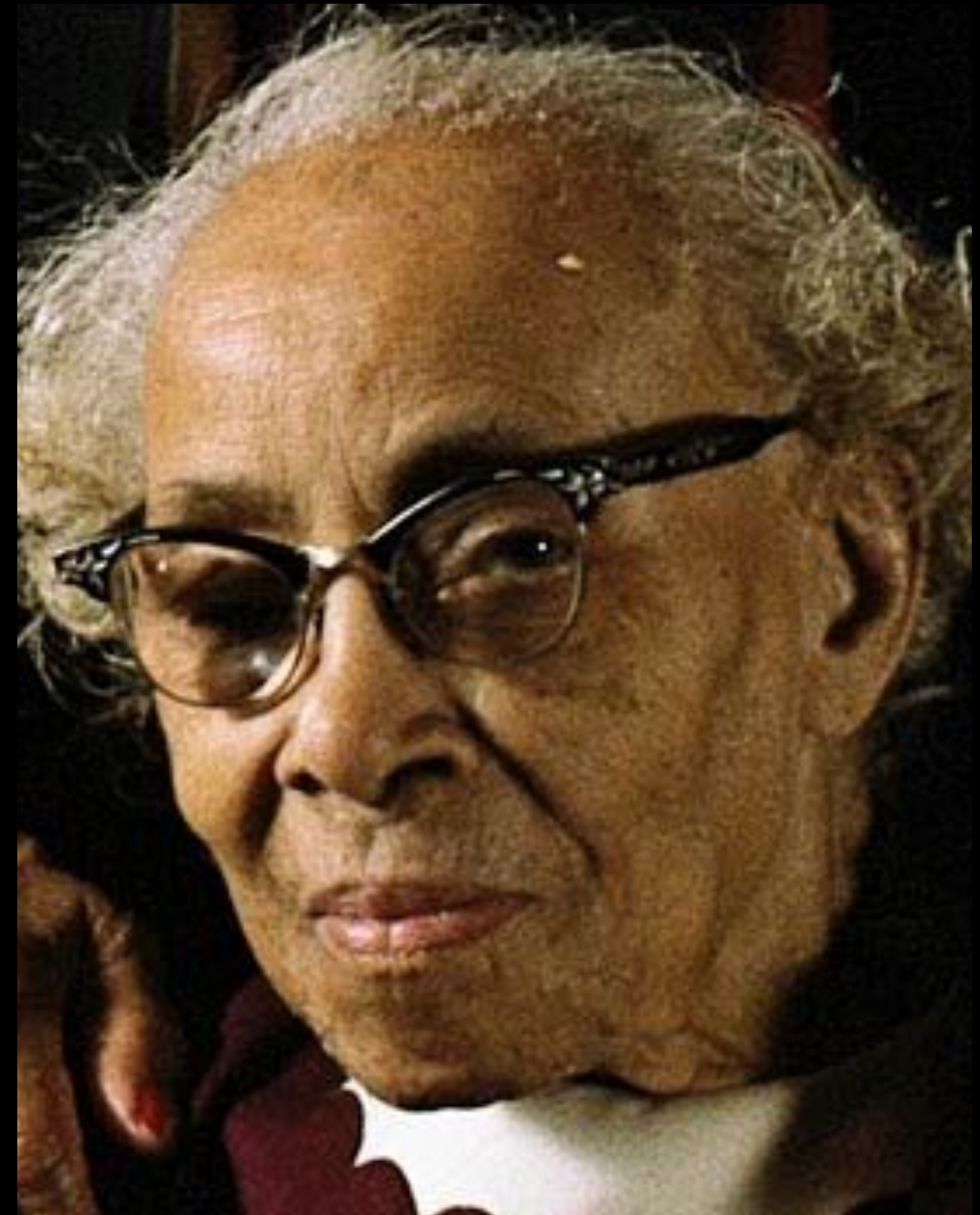
- Revisit the importance of diversity in research
- Describe history of barriers to clinical research for Black participants
- Review practical and creative solutions to inclusive research design





# Goals for this talk

- Revisit the importance of diversity in research



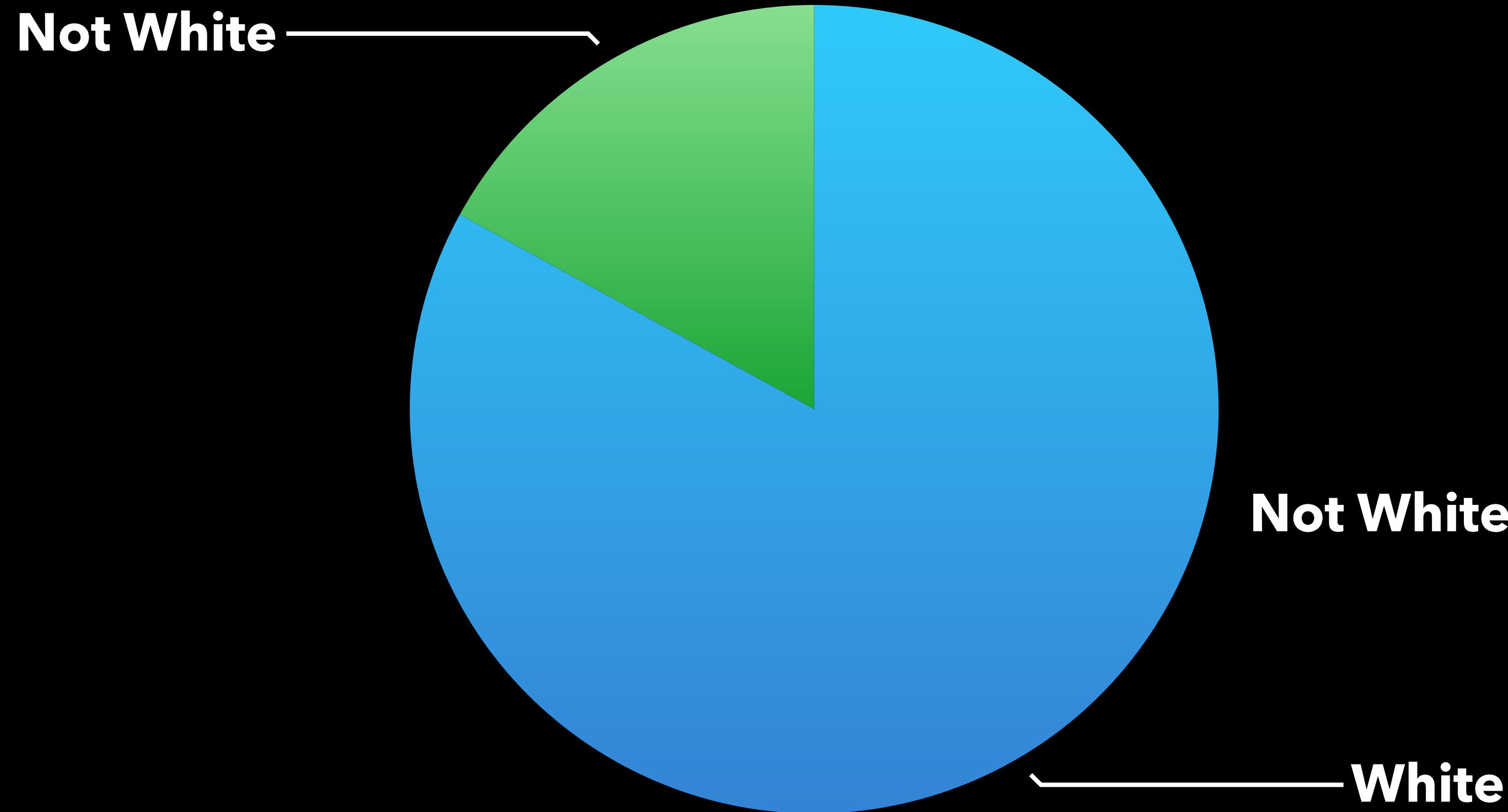


# Why is diversity crucial for clinical research?

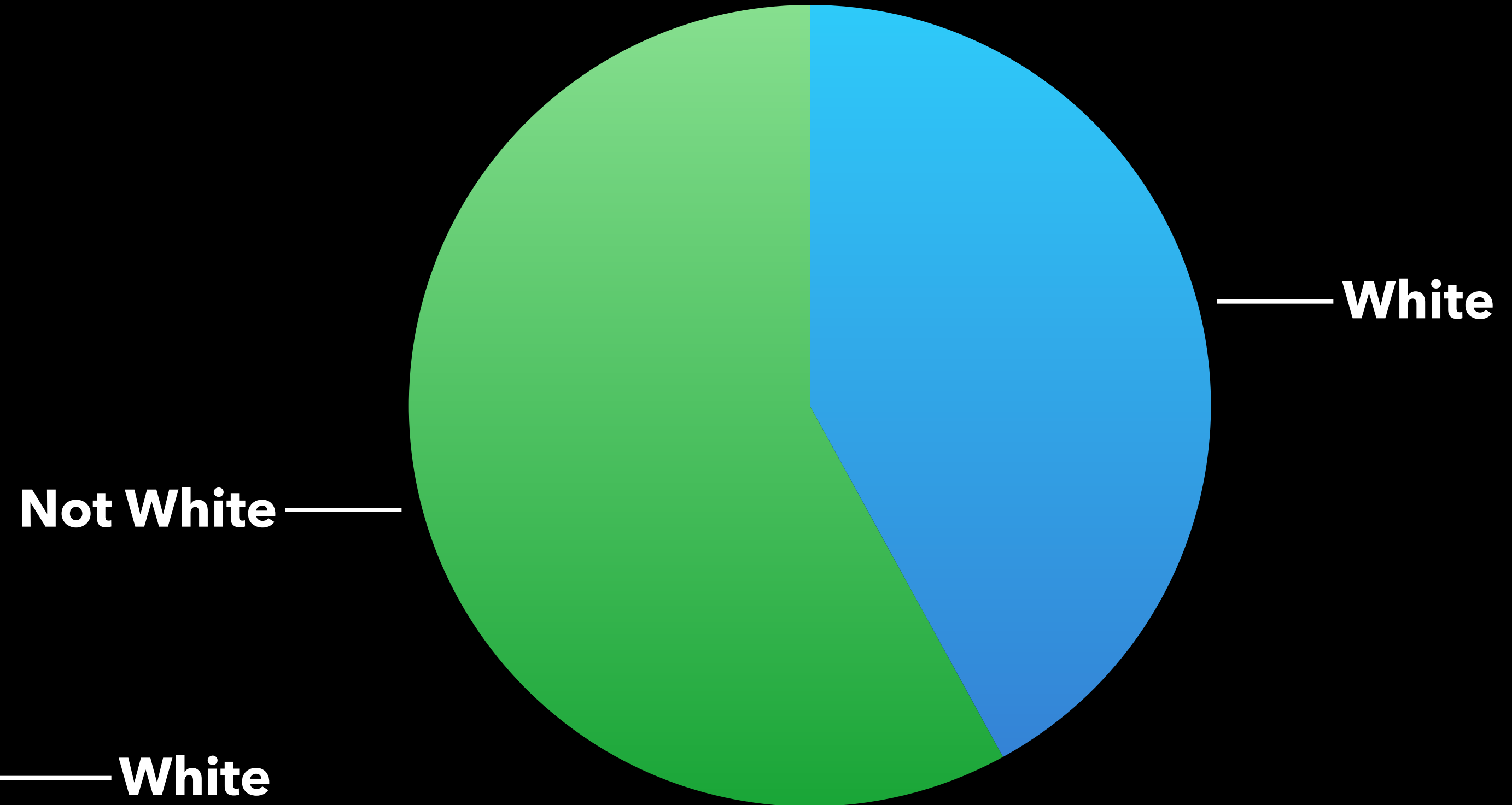
- Current enrollment statistics show very low levels of minority participation in Boston area

# Why is diversity crucial for clinical research?

MGH participants



Boston demography

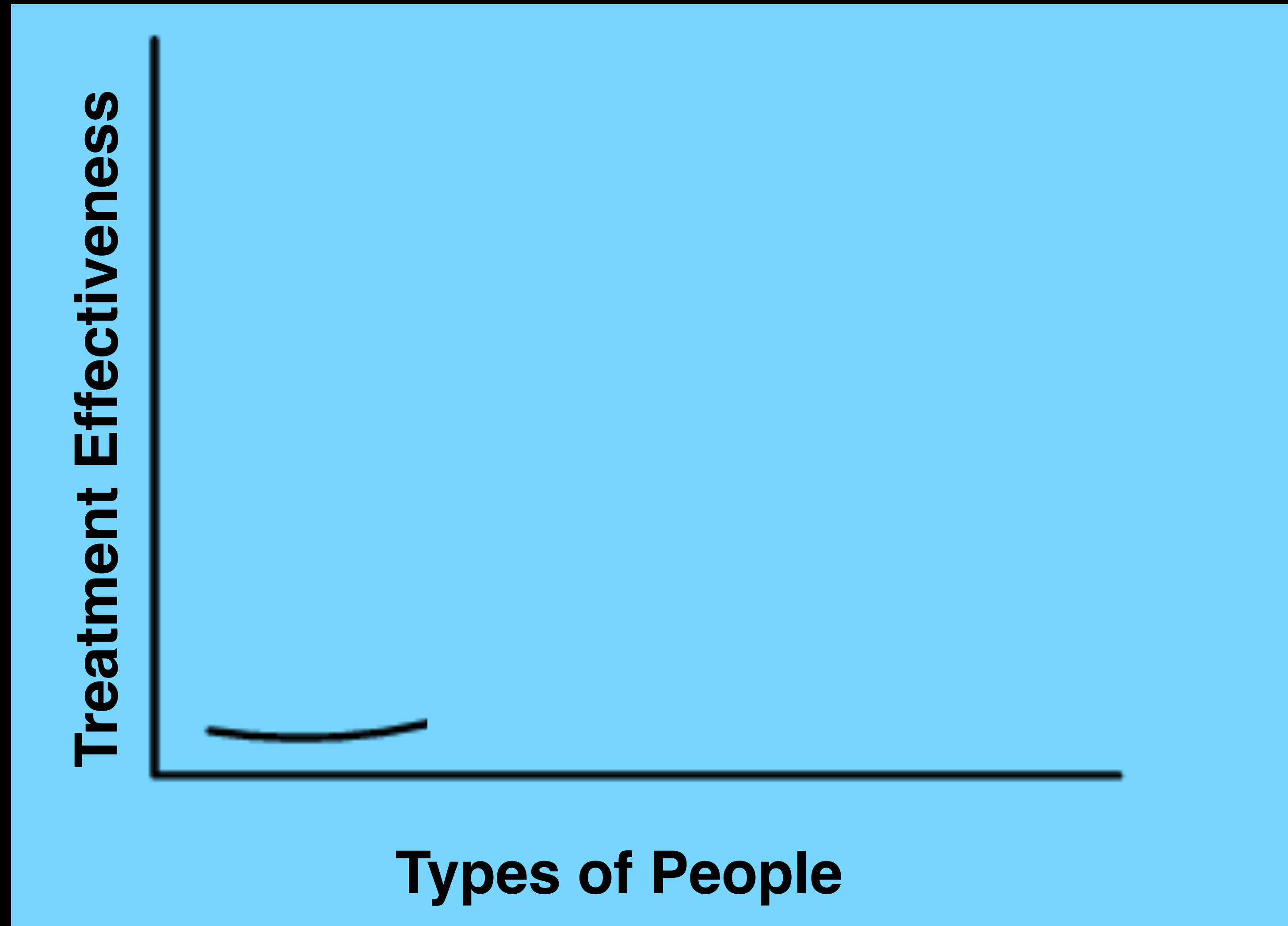


# Why is diversity crucial for clinical research?

- Current enrollment statistics show very low levels of minority participation in Boston area
- 1 in 5 drugs approved by FDA showed differences in exposure / response as a function of racial / ethnic group (Ramamoorthy et al., 2015)



# Why is diversity crucial for clinical research?

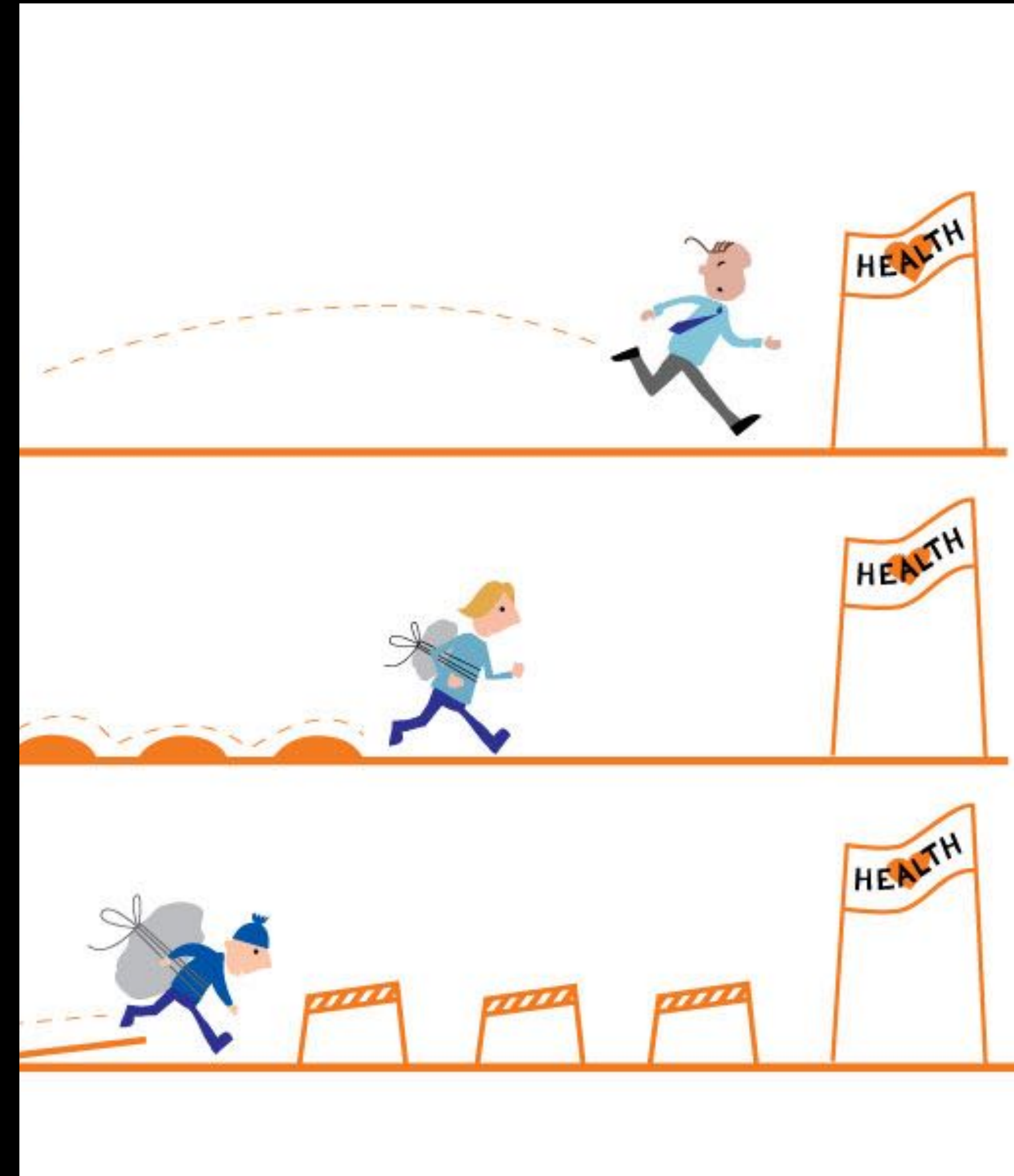


# Why is diversity crucial for clinical research?

- Current enrollment statistics show very low levels of minority participation in Boston area
- 1 in 5 drugs approved by FDA showed differences in exposure / response as a function of racial / ethnic group (Ramamoorthy et al., 2015)
- “Noise” as signal - provides much-needed statistical variability for robust models

# Goals for this talk

- Describe history of barriers to clinical research for Black participants





# The New York Times

© 1972 The New York Times Company

NEW YORK, WEDNESDAY, JULY 26, 1972

## *Syphilis Victims in U.S. Study Went Untreated for 40 Years*

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By **JEAN HELLER**

The Associated Press

WASHINGTON, July 25—For have serious doubts about the  
40 years the United States Pub- morality of the study, also say  
the Health Service has conducted that it is too late to treat the





Source: Nova, PBS, 1993

# Other medical abuses against Blacks

- Samuel Cartwright (1840s) - *coined drapetomania and dysthaesthesia aethiopica to justify slavery*
- Marion Sims (1850s) - *learned to repair prolapsed uteri on Black slaves without anesthesia*
- Joseph Goldberger (1912) - *induced pellagra in prisoners*
- American South (1920s) - *medical use of “idiot,” “imbecile,” & “moron” to force sterilization of Blacks*
- George Gey (1951) - *took Henrietta Lacks’ cells without consent, created HeLa immortal cell line*
- Chester Southam (1952, 1963) - *injected cancer cells in prisoners*
- **Vertus Hardiman (1925)** - *skull dissolved after being irradiated as 5 year old, parents deceived*
- **Ebb Cade (1941)** - *injected with plutonium, denied medical care after severe car accident*
- Eugene Saenger (1960-1971) - *forged consent documents, irradiated patients*
- Johns Hopkins, 1970 - *misled participants, looking for genetic predisposition to crime*
- Centers for Disease Control, 1990- *experimental measles vaccines for babies without consent*
- Columbia University, 1997 - *broke sealed juvenile records, specifically excluded Whites*



# Abuses give way to disparities

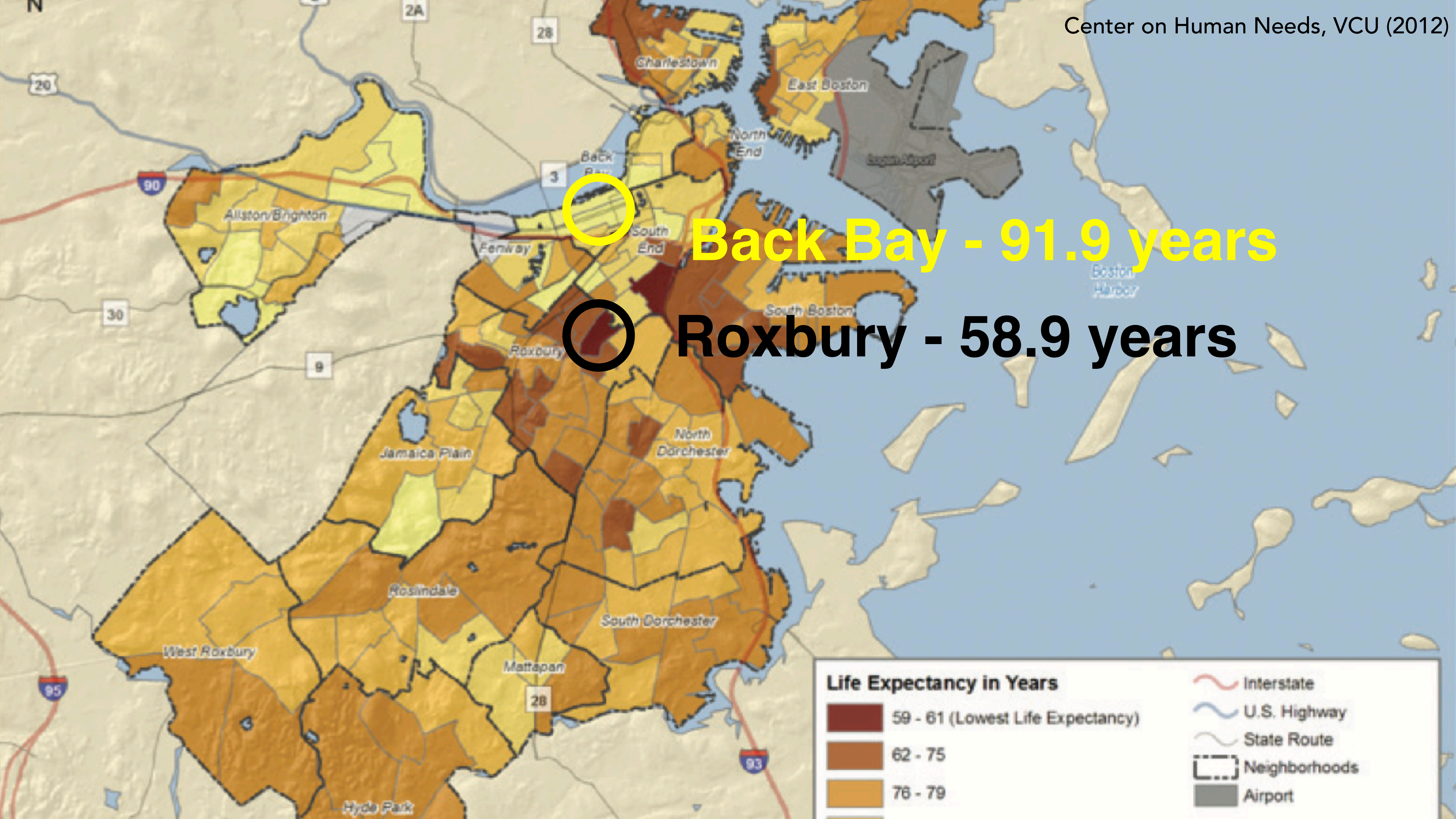


## Infant mortality | Deaths per 1,000 infants

NCHS, National Vital Statistics System, 2015







Back Bay - 91.9 years

Roxbury - 58.9 years



# The Belmont Report (1979)

- Respect for Persons
  - Must provide informed consent
- Beneficence
  - Do no harm
  - All parties must understand and accept risks/benefits
- Justice
  - Fair distribution of costs and benefits



# How does the federal gov't encourage diversity?

- NIH Revitalization Act of 1993
  - Assumption of research that reflects US population
- NIH Policy - Inclusion of Women and Minorities 2001
  - Must explicitly consider women/minorities in study design
- Establishment of Special Populations offices at NIH
  - Funding and frameworks for diverse samples
  - Other recent restructuring across ICs

# And yet...

Table 1. Demographic Subgroups in 2017

FDA Clinical Trials Snapshots (2017)

DEMOGRAPHIC SUBGROUPS	WOMEN	WHITE	ASIAN	BLACK or AFRICAN AMERICAN	HISPANIC
PARTICIPANT AVERAGE	55%	77%	11%	7%	14%

Est US pop	50.8%	76.6%	5.8%	13.4%	18.1%
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# And yet...

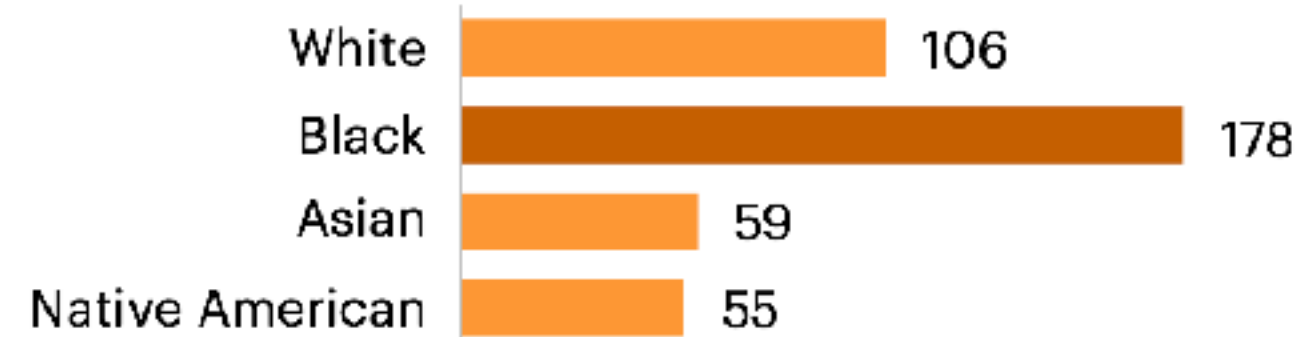
## Black Patients Miss Out On Promising Cancer Drugs

A ProPublica analysis found that black people and Native Americans are under-represented in clinical trials of new drugs, even when the treatment is aimed at a type of cancer that disproportionately affects them.

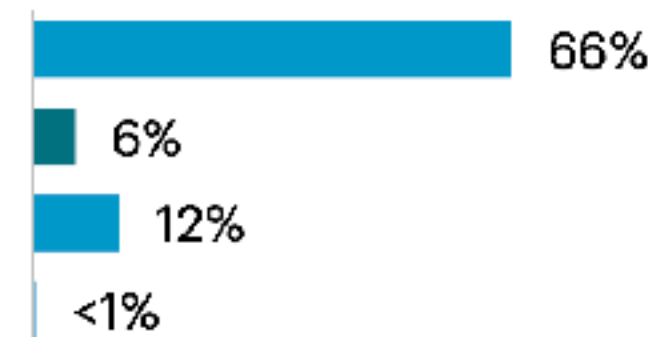
by Caroline Chen and Riley Wong, Sept. 19, 5 a.m. EDT

### Prostate Cancer

New Cases of Prostate Cancer,  
Per 100,000 People



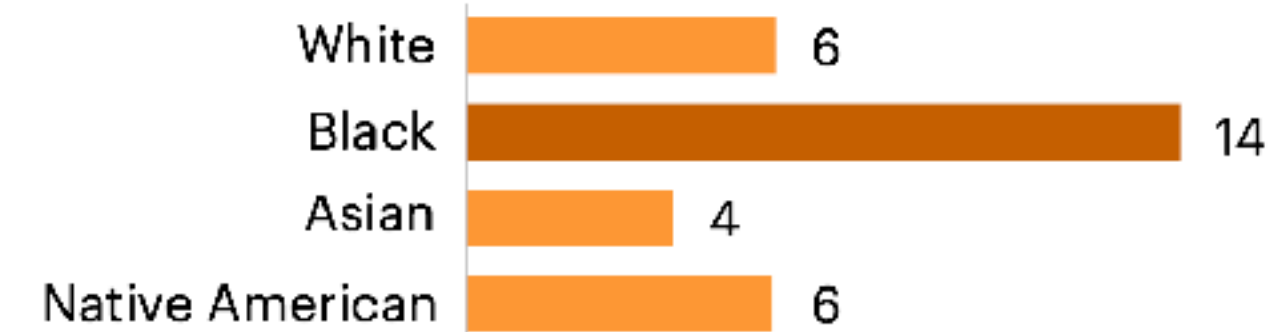
Erleada: Representation in Clinical Trials



**Note:** For 16 percent of Erleada's clinical trial participants, race was not reported.

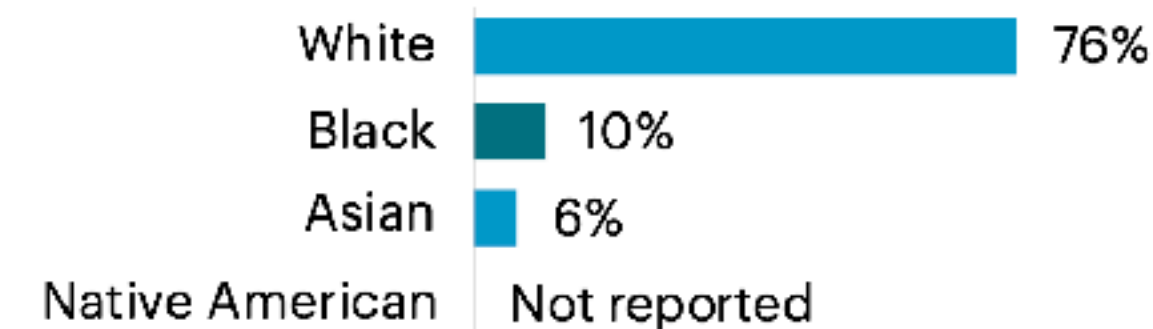
### Black Americans Face the Highest Risk of Multiple Myeloma but Are Underrepresented in Trials Treating the Cancer

New Cases of Multiple Myeloma, Per 100,000 People

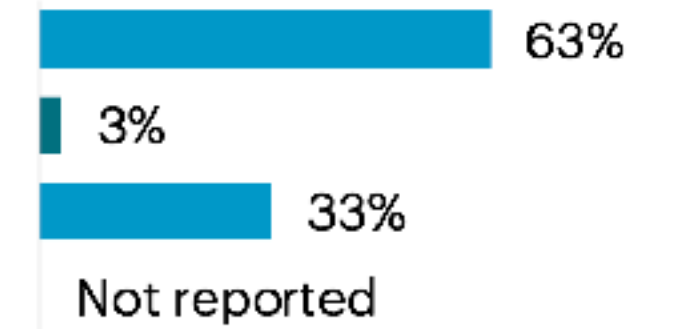


Representation in Clinical Trials

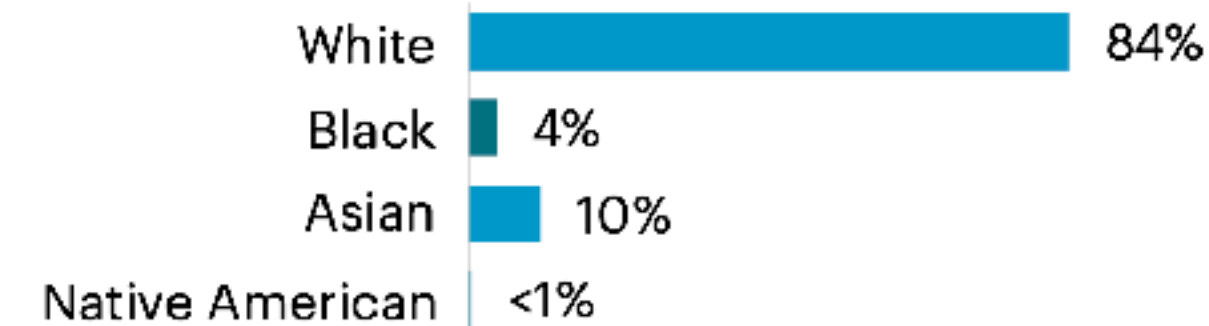
Darzalex



Farydak



Empliciti



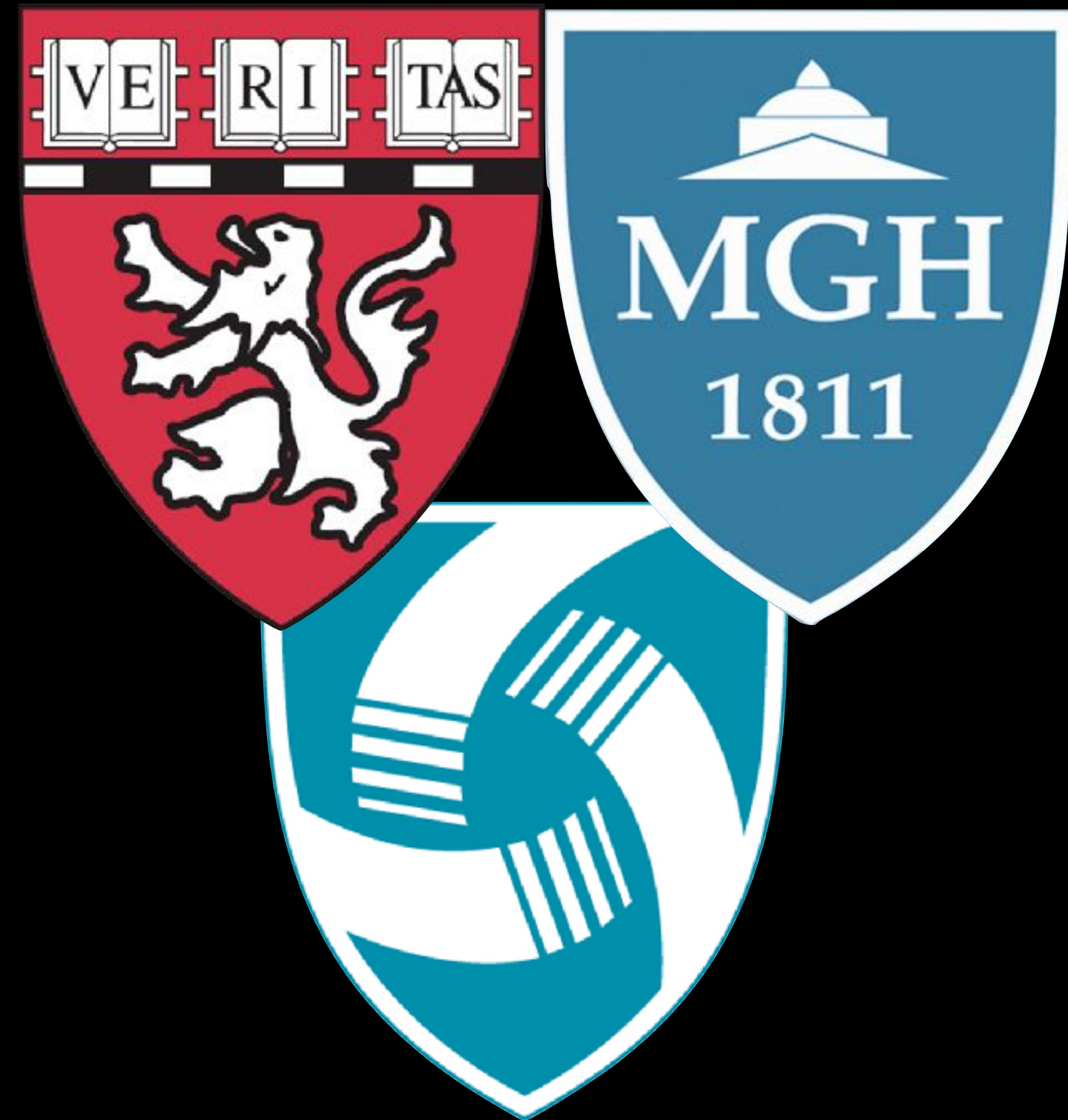
Ninlaro



**Notes:** Race was not reported for 8 percent of Darzalex's clinical trial participants, and 4.7 percent of Ninlaro's clinical trial participants.

# Goals for this talk

- Review practical and creative solutions to inclusive research design



# The importance of recruitment planning

1. Many studies fail to meet enrollment (IOM 2010)
2. Enrollment is often (pick at least one):
  - a. slow
  - b. homogenous, or
  - c. over budget
3. We often unknowingly build in barriers to participation
4. NIH/FDA are getting stricter on this in recent years
5. It's an easy thing to add to your innovation sections



# Barriers experienced by Blacks

1. Lack of awareness of research opportunities
2. Deep mistrust of healthcare system and research studies
3. Confusion and concern over what research is
4. Limited transportation options / times
5. Inclusion / exclusion criteria
6. Lack of plain language use in documents
7. Fear of placebo / fear of intervention
8. Health insurance coverage
9. Limited diversity on study staff

Bonevski et al 2014, *BMC Med Res Method*  
George et al 2004, *Am J Public Health*  
Jackson Moy Evans 2016, *The Oncologist*  
Oh et al 2015, *PLoS Medicine*

But frankly, it's not just  
about *race*

# Planning a dementia-friendly meeting

1. Find a venue that's easy to get to. The entrance to the building should be obvious.

Travel details should be given to people well beforehand.

2. Have someone at the door to greet people and let them in.

3. Ensure that rooms are light and airy, and that signposts are large and clear.

4. Consider the sound quality in the room.

5. Make sure there is enough distance between tables so people can hear discussion on their own table.

6. Think about whether there are enough toilets, and how easy they are to find.

7. Consider catering the meeting, both as a break and to offer refreshment

# MADRC's experiences in diverse recruitment

- Massachusetts Alzheimer's Disease Research Center
  - Founded 1984, funded by P50 center grant
  - Currently focused on early detection and prevention of Alzheimer's disease
- Organized under six Cores
  - Core E - Outreach, Recruitment, & Education
  - Extremely limited resources until 2016

# MADRC's challenges in diverse recruitment

- No existing clinical registry / cohort
- Strong staff resistance / dep't apathy
- Non-diverse study staff
- Low-accessibility site
- No resources / personnel to dedicate to efforts
- Poor reputation among minority communities
- Study inclusion / exclusion criteria screen-failed minorities
- “Competition” from nearby AD research center, historically closer to Blacks

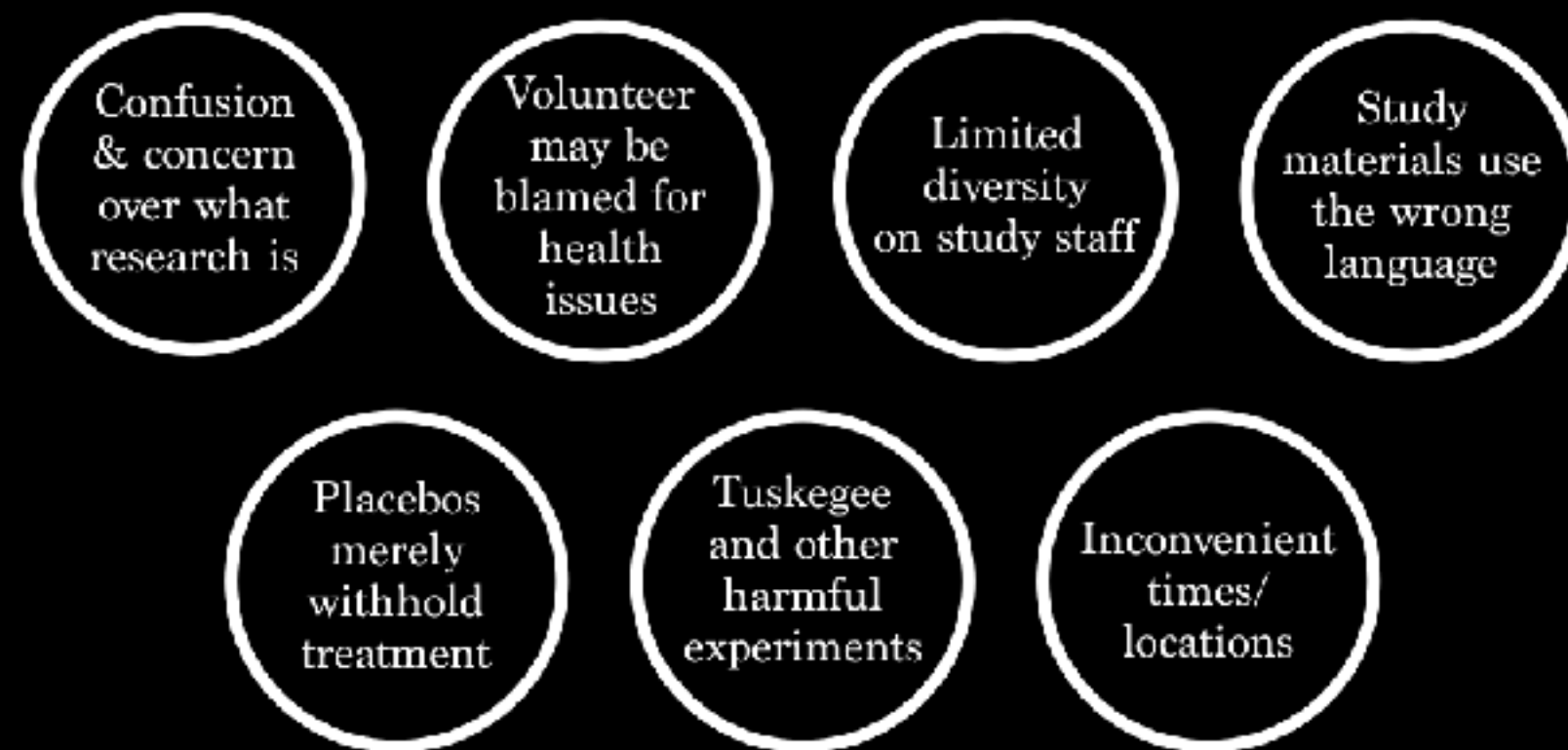




# Internal strategy

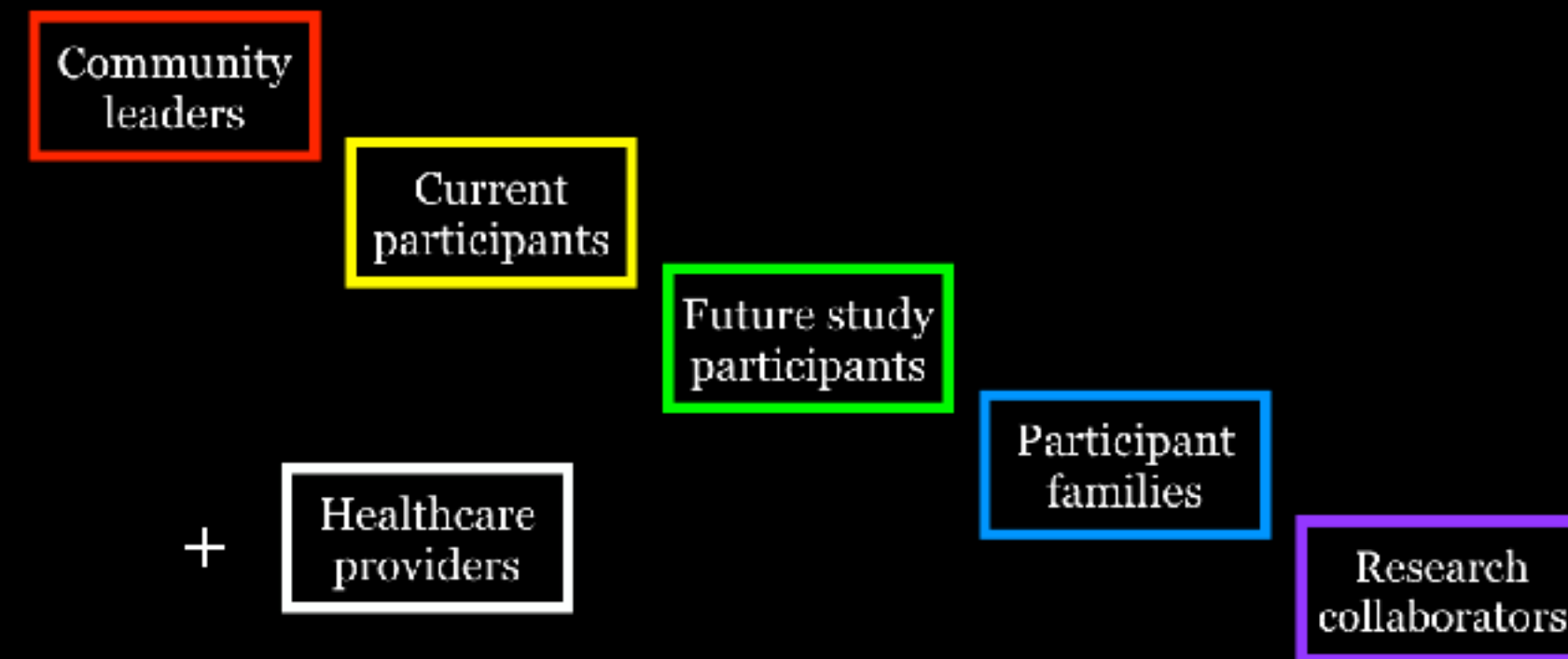
What's Happening Now	Agents of Change		Goals		
	Actions	Actors	Short	Medium	Long

What are some barriers to research?



What's Happening Now	Agents of Change		Goals		
	Actions	Actors	Short	Medium	Long

Who should be involved in this process?



What's Happening Now	Agents of Change		Goals		
	Actions	Actors	Short	Medium	Long

What short-term goals can we agree on?  
(6-9 months)

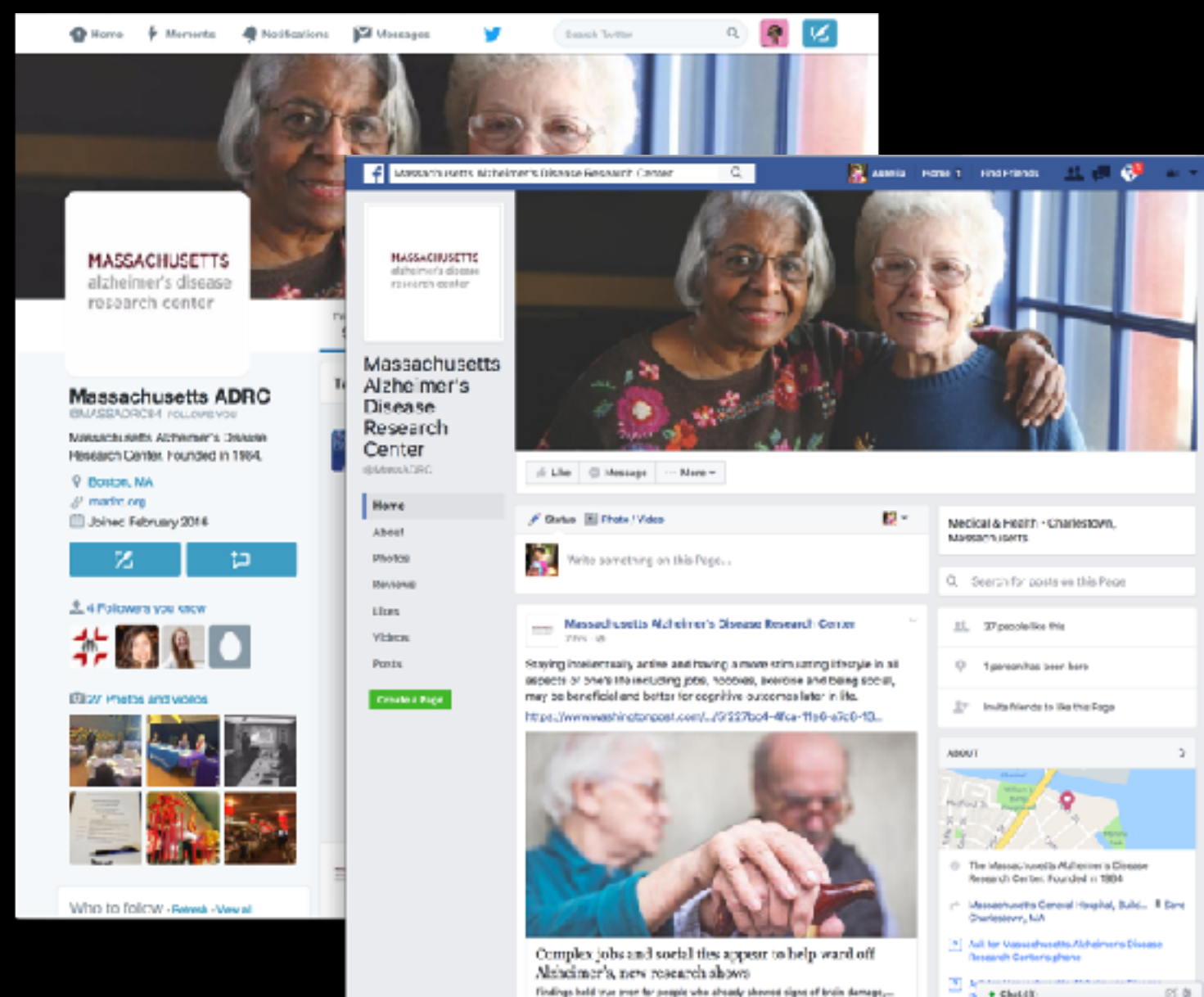


# Internal strategy

- Established a Community Advisory Board
  - Reached out to community health advocates
  - Met at least quarterly
  - Spent more time listening than talking
- Dedicated (lots of) time, and *sustain* it
  - Estimated time, then added order of magnitude (yes, really)
  - Attended, sponsored, organized hundreds of community events
  - Reached out to primary care and specialists - offered support, not pamphlets
  - Strong social / digital media presence
  - Research ambassador program
  - Ensured broad departmental support

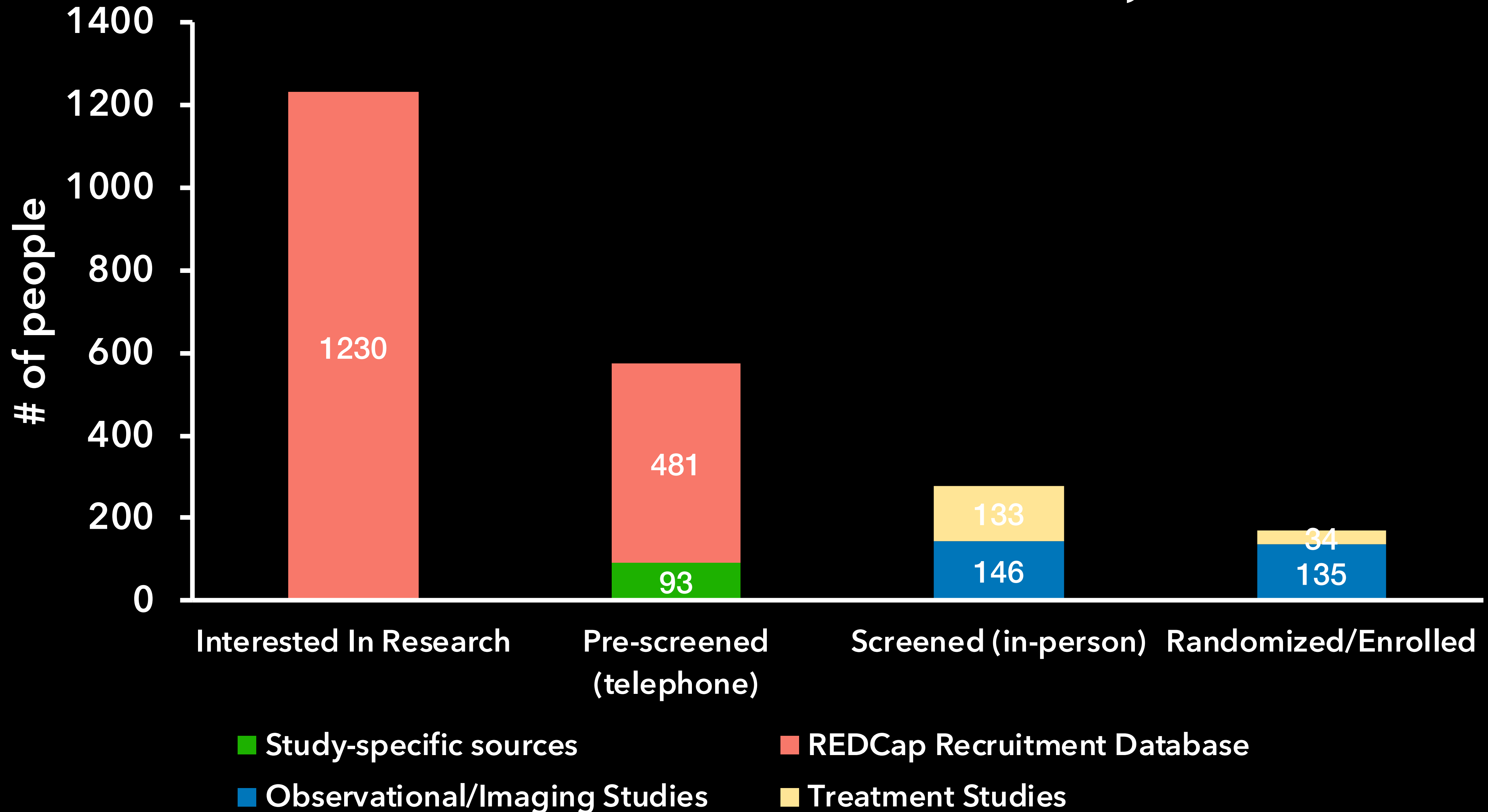


# Internal strategy



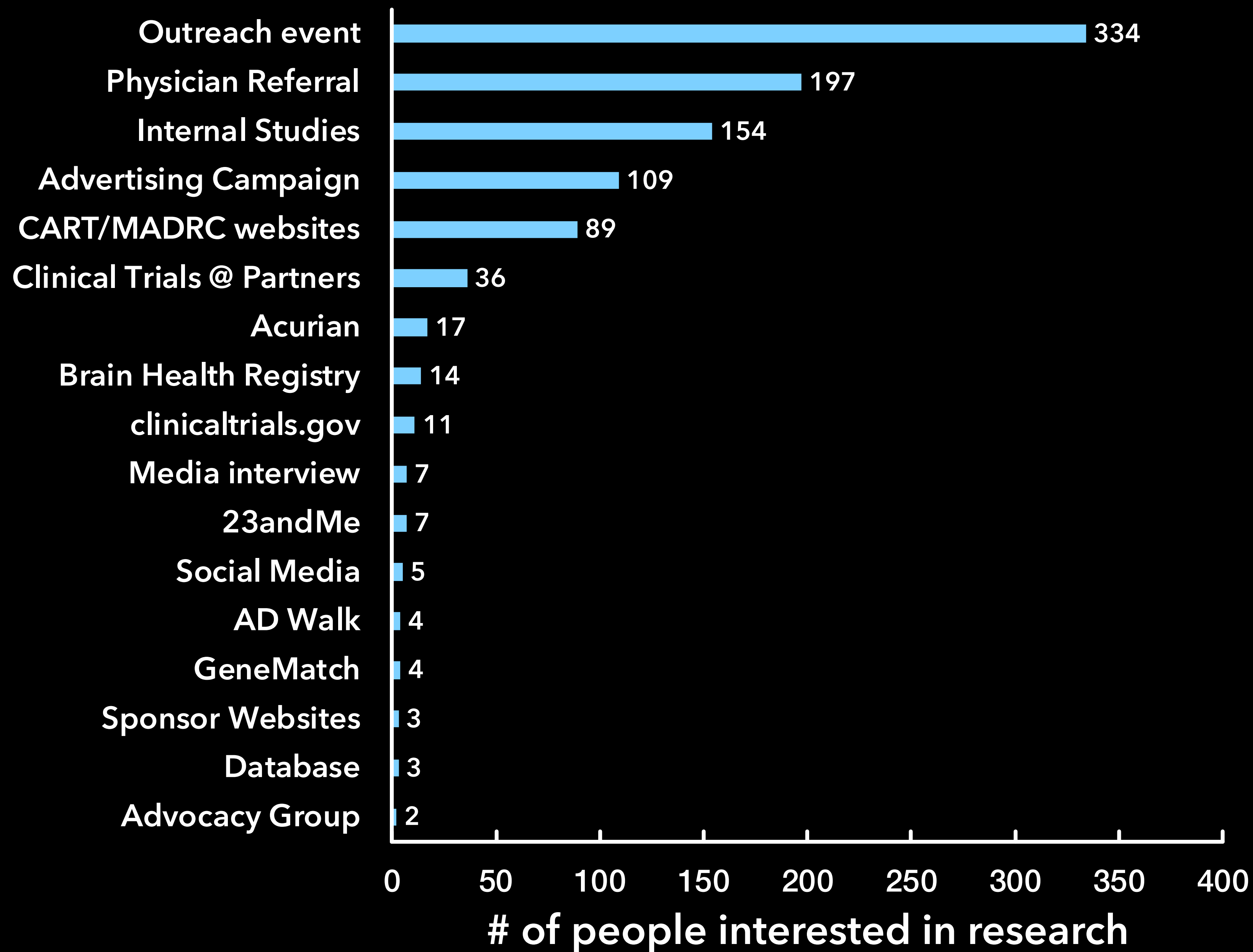


# MADRC Recruitment, 2017





# MADRC Recruitment, 2017



# Advice for committed triallists

- Diversify staff at all levels
  - Hire people of color, but don't place burden only on them!
- Recognize and reduce barriers to clinical care
  - Consider reducing reimbursement burden
  - Make (and pay for) transportation arrangements
  - Partner with clinics for routine work
  - Revisit protocol and documentation - what can be made simpler?
- Be humble. Be transparent.

# Advice for committed triallists

- Recognize diversity within diversity
  - African-American / Black / Hispanic / Latino / People of Color
- Listen. Listen. Listen.
  - May not be fair, but burden is on study team
- Become *fictive kin*
  - Focus on education and empowerment
  - Stick around - this is a partnership, not a harvest



# Some basic suggestions

1. It is SO MUCH EASIER to figure this out beforehand than after
2. Set small & interim goals. Tie these to social media and digital platforms
3. Set a fifth-grade reading level for all communications
4. Get sustained face-time with clinicians and community
5. Think about recruitment tools you'll use and assumptions behind them
6. Review inclusion/exclusion criteria. Try to allow *more* people to participate
7. Can't just aim for representative sample; try enriching for vulnerable pops
8. Hire some *local* folks at all levels of the research team
9. Be transparent. Be humble. You are not doing anyone a favor.

# Here are some ideas to get you started

- Sponsor ads on local radio (*not* NPR) & print media
- Bring back past participants as ambassadors
- Consider payment for screening visit
- Avoid deficit-model framing (i.e., talk about resilience not disparities)
- Translate (and simplify) study materials
- Sponsor health fairs
- Offer CMEs / training to neighborhood clinics
- Serve on community boards
- Include families in recruitment & consent
- Patient navigation / advocacy
- Enrich social media with Q&As, interviews, featured research
- Partner with other study teams for screen-fails
- Talk to someone (literally anyone) from targeted communities
- Share research results
- Develop community talks

**Safe space for awkward  
questions about diversity**

**Don't feel embarrassed or ashamed!**

**We're all here to learn!**