

# Participants' perspectives and the evolution of genomic data sharing policies

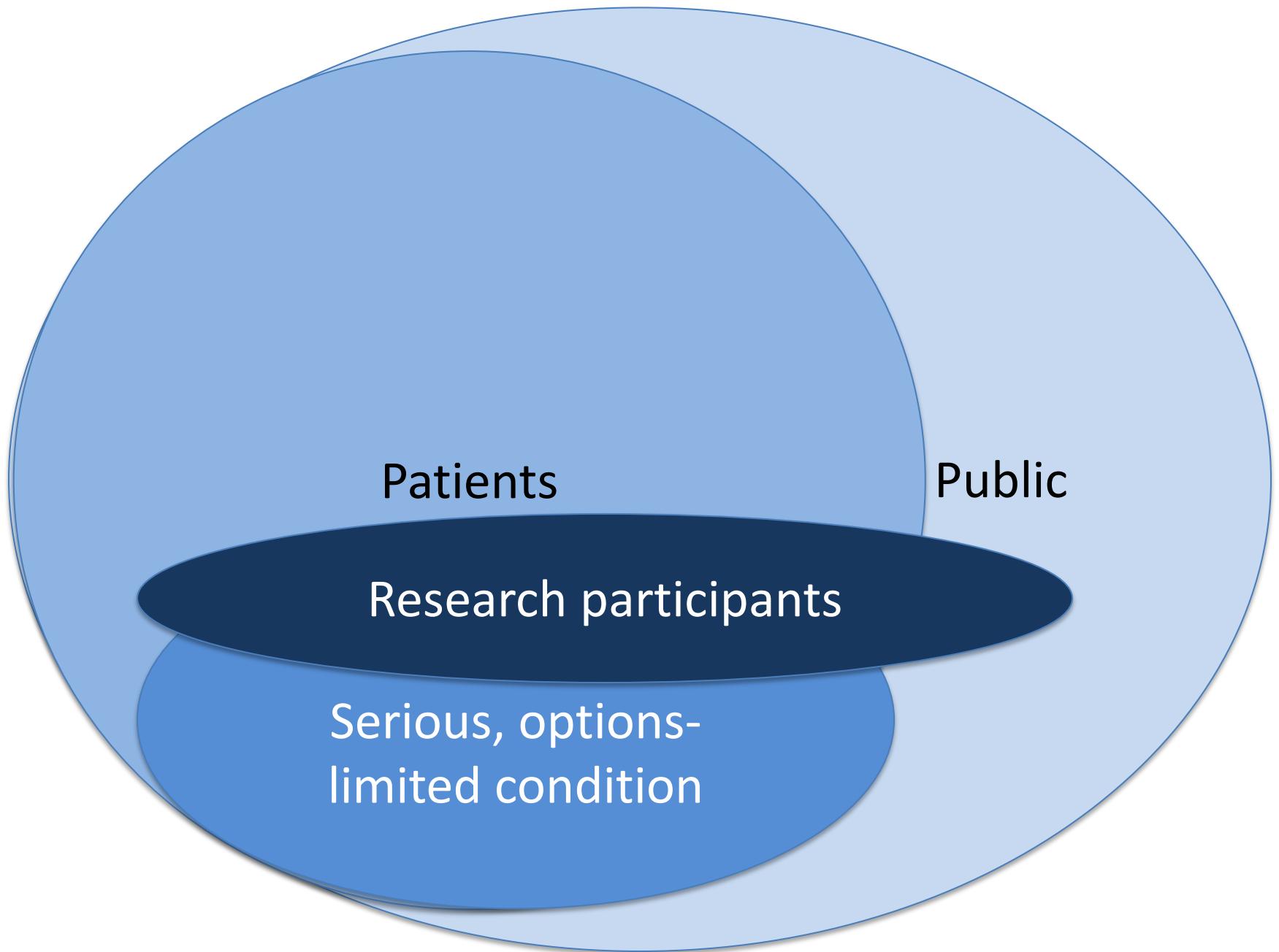
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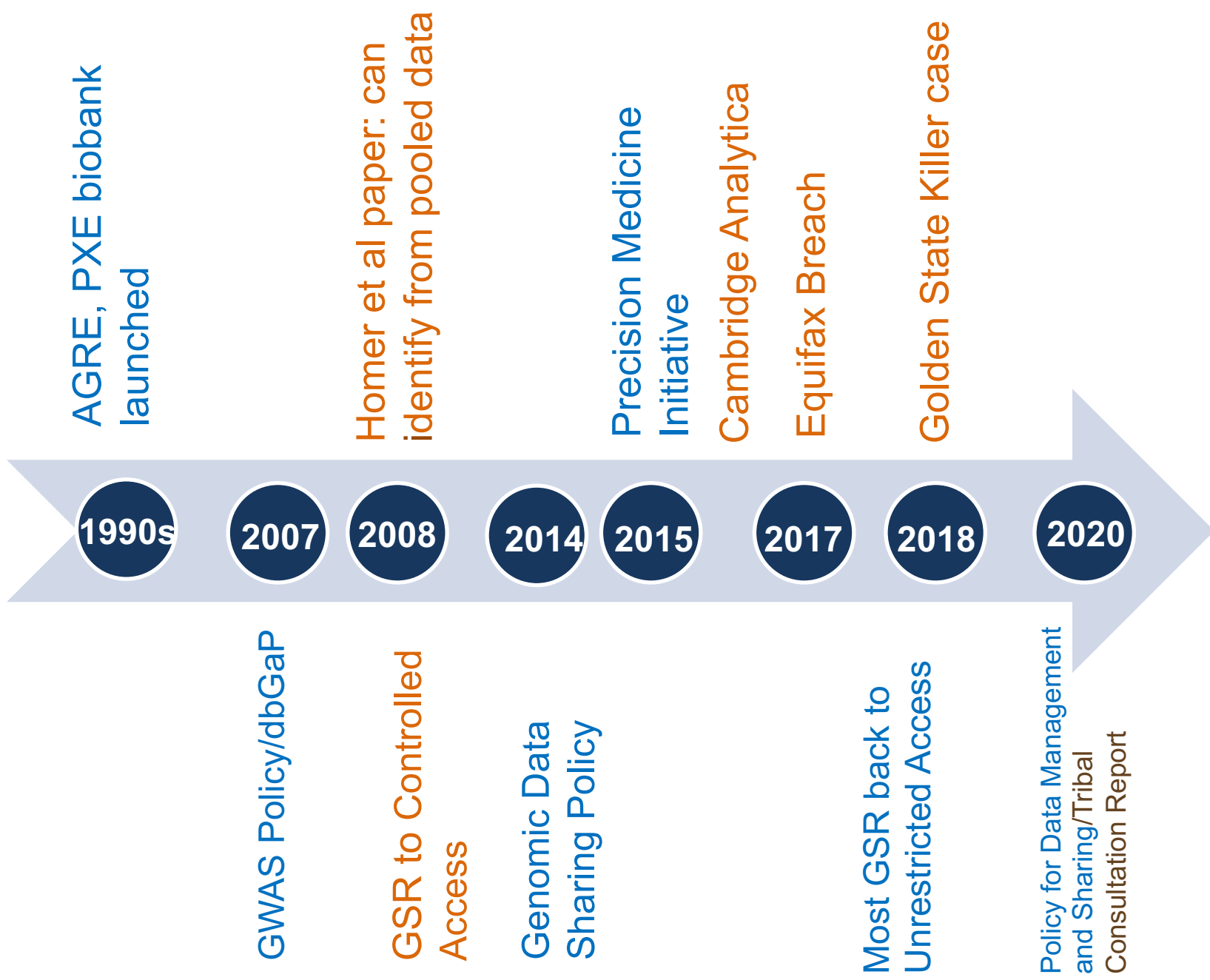
# Overview

1. Setting the stage
2. Findings from research
3. Implications?



## NIH Policies

## Events



## Open

## A systematic literature review of individuals' perspectives on broad consent and data sharing in the United States

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**Purpose:** In 2011, an Advanced Research and Practice Center (ARPC) proposed that de-identified data in biobanks only if patients provide informed consent. The Centers for Disease Control and Prevention (CDC) of Health Genomic Data Storage (HGDS) requiring broad consent from

**Methods:** We conducted a systematic review of the literature toward biobanking, broad consent, and data sharing. Databases included MEDLINE, Embase, and GenETHX. Study screening was performed by two reviewers.

**Results:** The final 48 studies (n = 8), mixed methods (n = 1), analyses (n = 2), Study quality was fair (n = 27), and poor (n = 2).

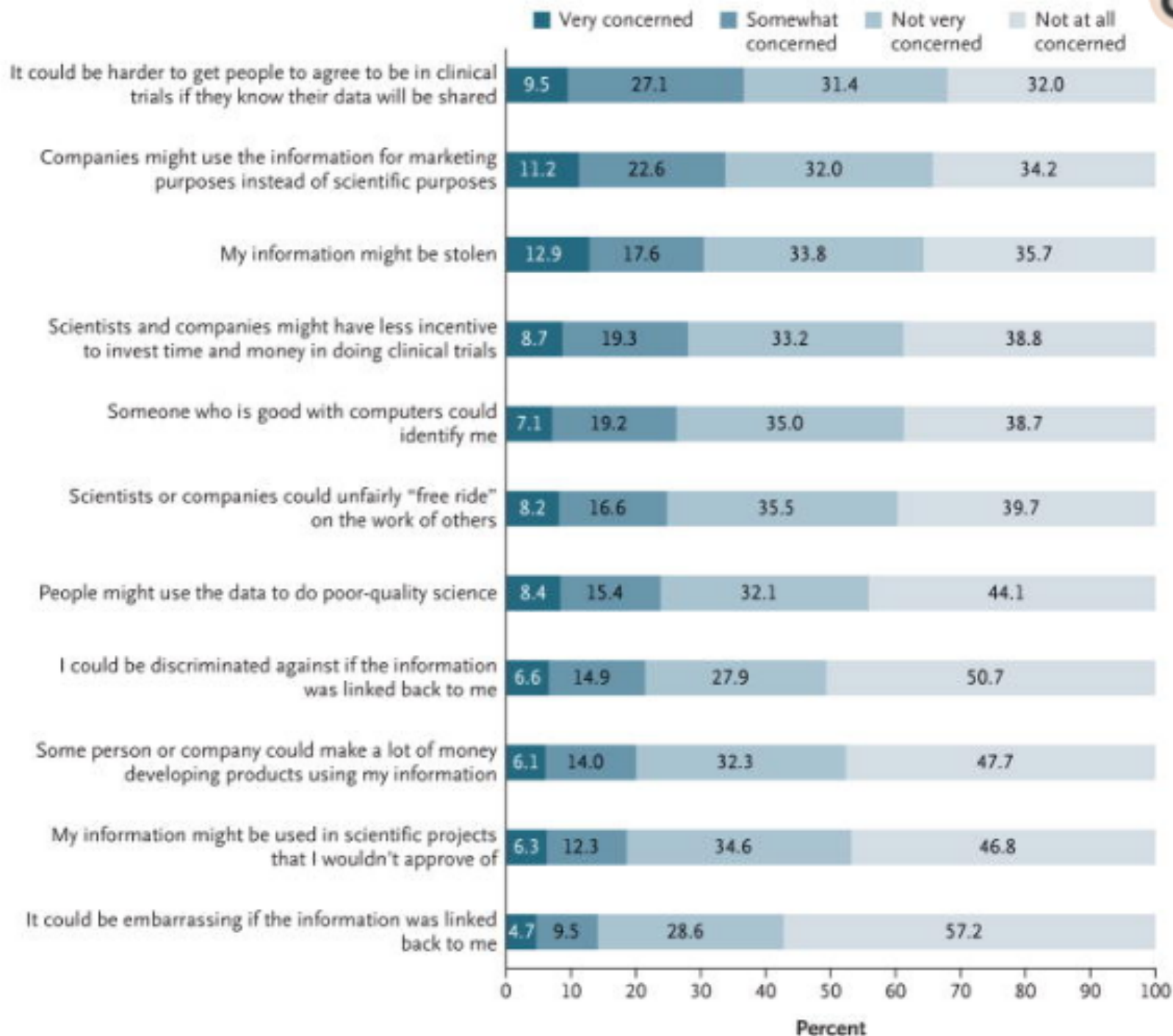
Vast amounts of genomic data are generated for many types of research. These data are often placed in databases which may exist at both the decentralized and centralized sites, and Phenotypes. These data have one purpose—whether for research or clinical care—frequently can be used for other purposes. These facts raise two distinct, but related questions: what conditions data can be shared in order to increase what can be learned from them. The second is whether data can and should be shared with other investigators in academic institutions, the government, and the commercial sector.

Currently, regulations for the protection of research participants and the Health Information Technology for Economic and Clinical Health Act amendments to the Health Insurance Portability and Accessibility Act Privacy Rule<sup>1</sup> permit the sharing and repurposing of data under certain conditions

While the majority often expressed support for broad consent when that was the only choice offered, only a minority of respondents favored broad consent when other options, such as tiered or study-by-study consent, were offered... Willingness to give broad consent increased if data were de-identified. While individuals were generally willing for data or biospecimens to be shared with other academic researchers, individuals were less willing for their data to be shared in federal databases or with commercial enterprises.

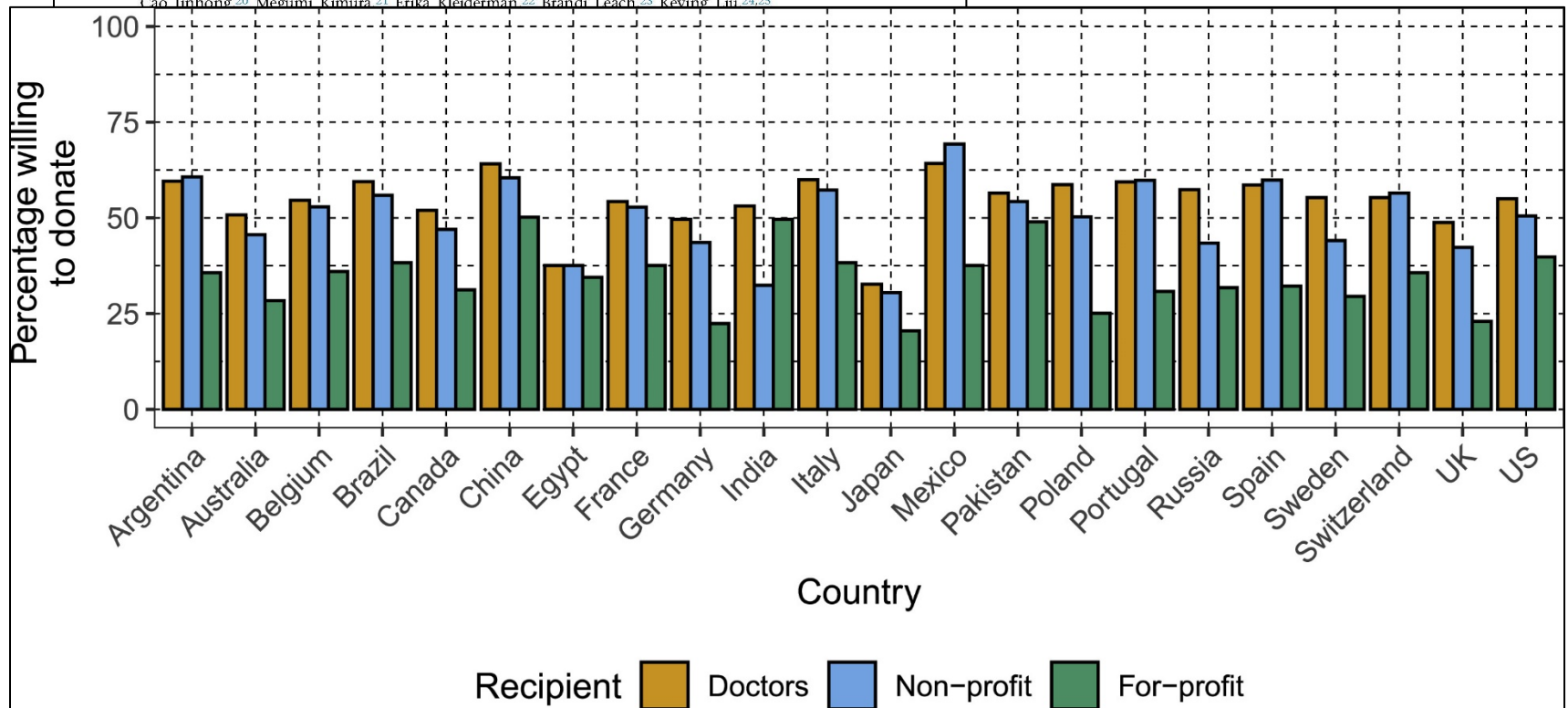
Nonetheless, questions remain about the ethical and practical desirability and acceptability of broad consent for research and data sharing. Approaches to obtain permission for use of genomic samples and data include no consent, opt-out, opt-in, case-by-case, tiered or categorical,<sup>4</sup> and broad or blanket consent. Many have argued that blanket consent for unanticipated future research uses is unethical<sup>5</sup> or unworkable,<sup>6</sup> whereas others argue that such consent is acceptable as long as additional protections are in place,<sup>7</sup> especially since broad data sharing

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# Global Public Perceptions of Genomic Data Sharing: What Shapes the Willingness to Donate DNA and Health Data?

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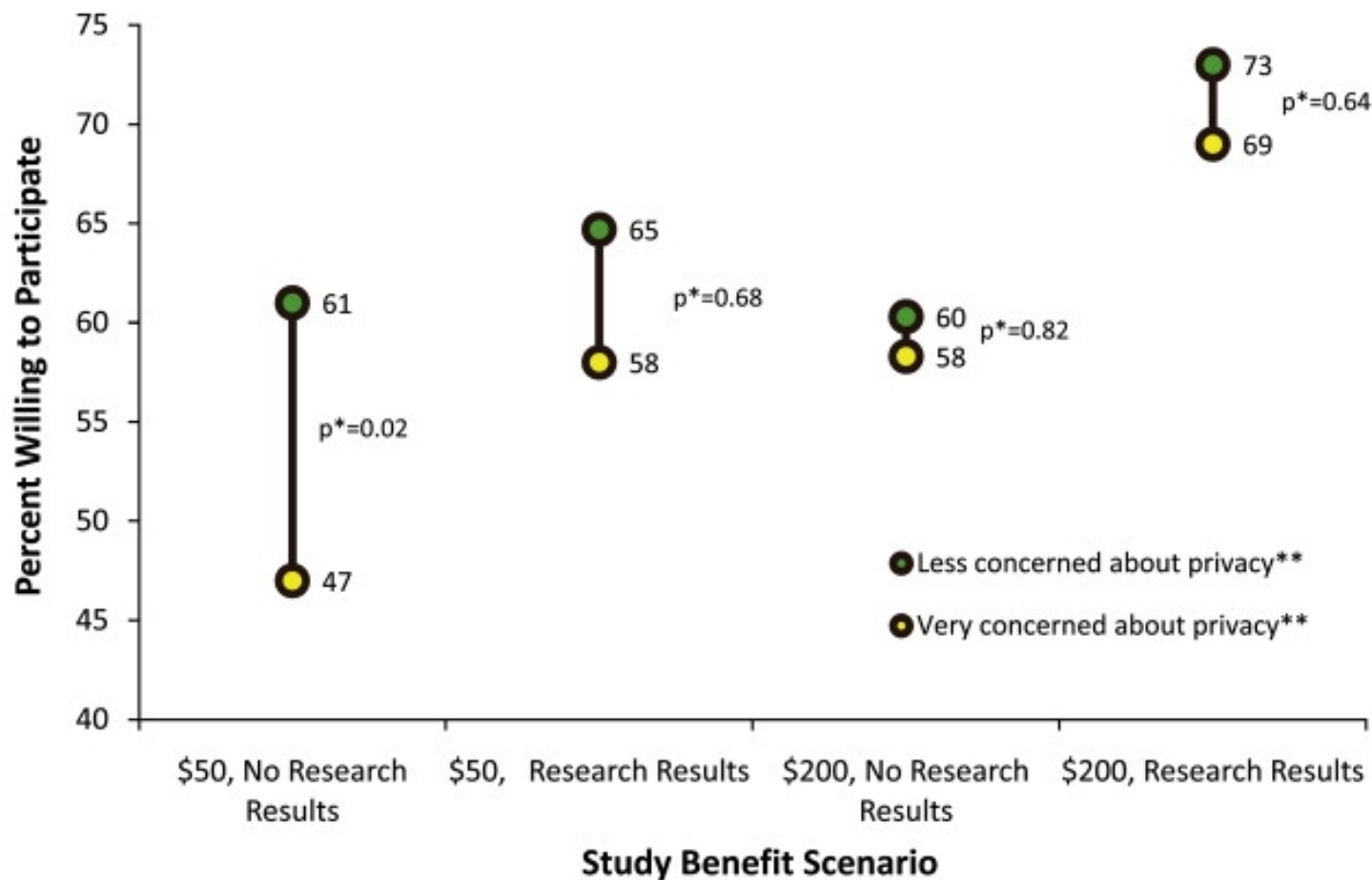
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\*p values are for the comparison of the odds that those less concerned with privacy would participate to the odds that those very concerned would participate, adjusting for age, gender, race and ethnicity, household income, and education.

\*\*These categories represent those who said they would be "very concerned" about "protecting my privacy" if they were participating in the study and those who said they would be somewhat concerned, a little concerned, or not at all concerned



Hopeful and Concerned: Public Input on Building Trustworthy Medical Information Commons

Patricia A. Deverka, ...  
Gilmore, Jennifer Ri ...  
Zachary Smith, PhD ...  
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Amy L. ...

To advance precision medicine and understanding of human health and disease, researchers, governments, private companies and patient groups are promoting the merits of collecting and sharing genetic, personal, environmental, and health-care data on a massive scale ("biomedical big data").<sup>1</sup> Maximizing the utility of these data requires networks of complementary data resources for both research and

Table 2  
Deliberant Hopes and Concerns

Hopes	Concerns
Benefit future generations	Breaches of data security and inability to protect individuals' privacy
Lead to ground-breaking medical advances (e.g. cure for cancer)	Accuracy and completeness of data
	that could unduly
	lack of diversity
	for
	on for
	by MIC
	ities
represent the publics interests	
Offer direct benefits/incentives to deliberants when possible	People would be cha...essing their information

1. No involvement

2. Feedback through surveys

3. Community advisory board

4. Participants on governing board

5. Participant-run with experts hired when needed

# Implications?

## Concerns/Consent

- Data hoarding violates the expectations and wishes of many participants
- Most participants prefer to be given choices, have reservations about sharing with for-profits, government
  - But in practice, most willing to consent to broad data sharing
- Not accommodating all consent preferences ≠ violating rights

## Context

- Steps can be taken to increase comfort/trust, demonstrate respect, and establish trustworthiness (e.g., return of value, care re access rules and other aspects of governance, vigilance re privacy and security)
- Especially important if aiming for more representative data resources

## Cautions

- Groups with cause for concern, sensitive research: special measures to involve and protect participants warranted