GENOMICS-ENABLED LEARNING HEALTH CARE SYSTEMS: GATHERING AND USING GENOMIC INFORMATION TO IMPROVE PATIENT CARE AND RESEARCH

TRANSLATION OF GENOMICS FOR PATIENT CARE AND RESEARCH – PATIENT'S PERSPECTIVE

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By 2017, 30% of US consumers will be wearing a device to track food, exercise, heart rate and other critical vital signs[1]

Over 500,000 consumers have directly purchased DNA testing services; no evidence of psychological harm, and some positive behavior changes[5]

In January 2014, nearly one-third of all US smartphone owners (46 million unique people) used fitness and health apps[2]

High percentage of consumers are concerned about the privacy and security of their medical information[3]

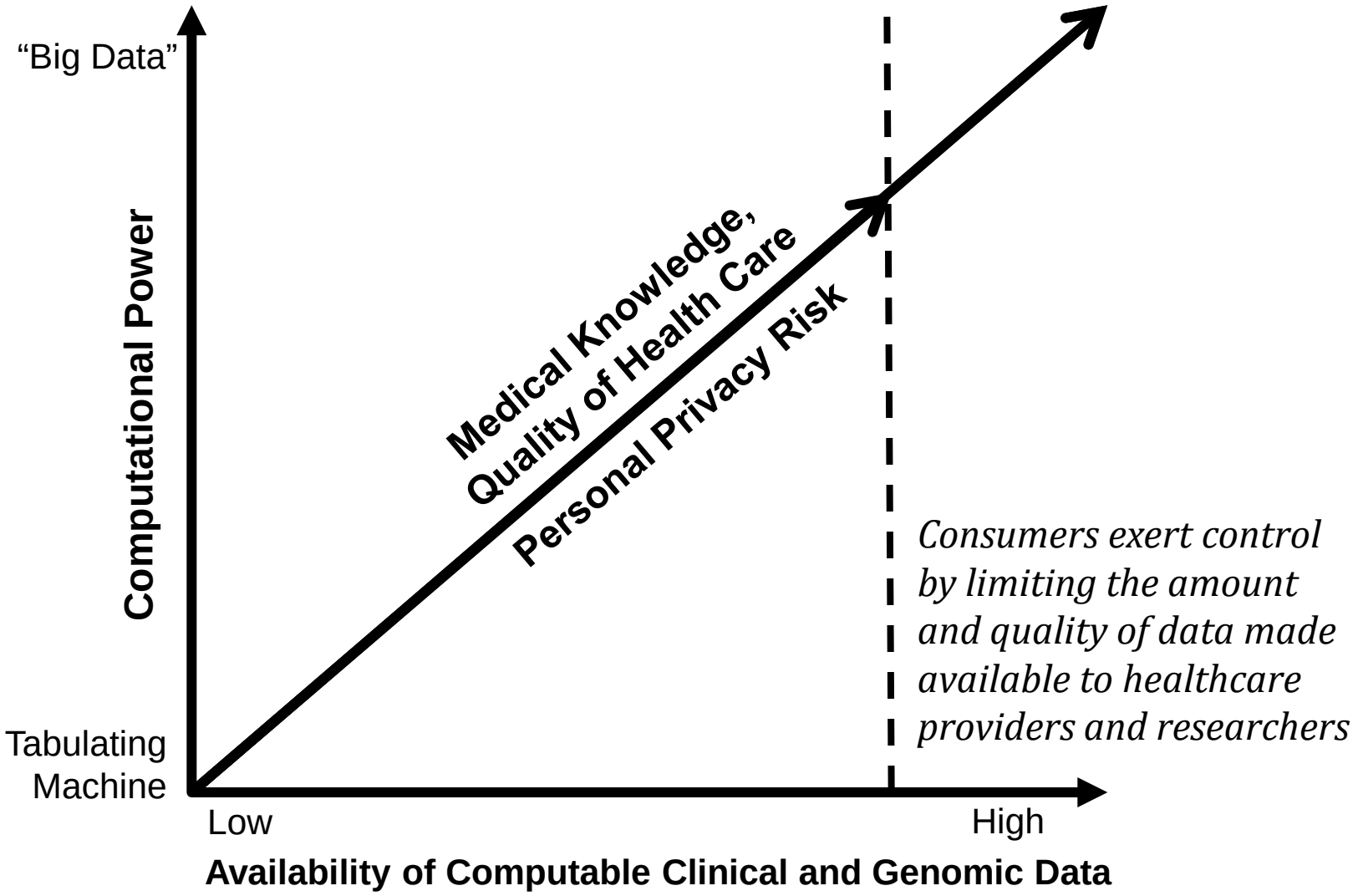
Today's Health Care Consumer

High percentage of US consumers want to control their health information, but roughly half believe they currently have very little control[4]

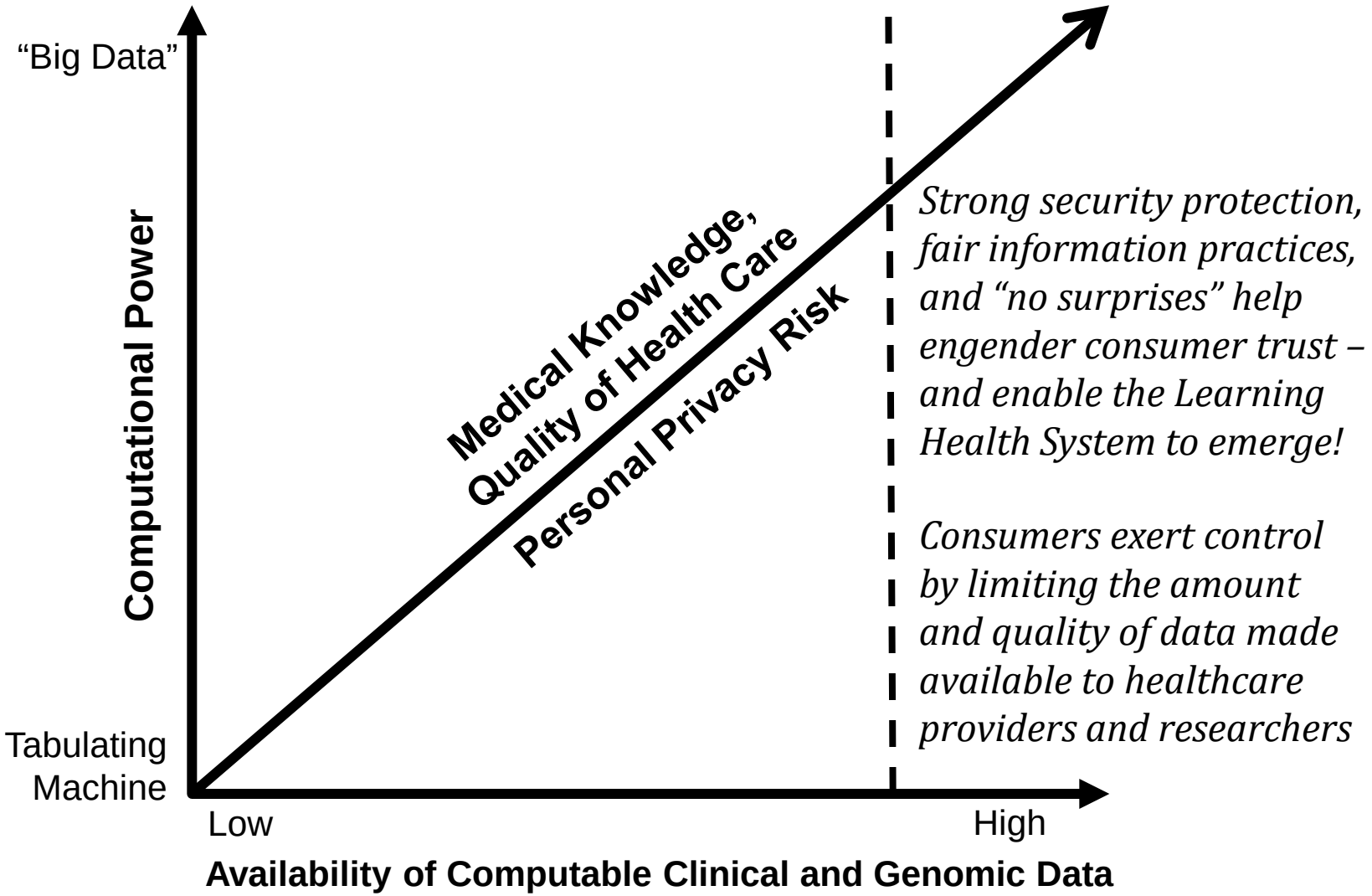
Consumers willingly contribute their data and biological samples to medical research – when their permission is sought[6] – security, transparency, control and "no surprises" are key!

[1]Tilenius, S. *Forbes.* 9/8/2013. [2] Nielson. 4/16/2014. [3] Patel, V. Office of the National Coordinator, Department of Health and Human Services. Nov 4, 2014. [4] Accenture. 2014 Patient Engagement Survey. May 14, 2014. [5] Green, R. and N. Farahany. The FDA is overcautious on consumer genomics. *Nature*. Jan 16, 2014. [6] Tarini, B.A., et al. Not without my permission: Parents' willingness to permit use of newborn screening samples for research. *Public Health Genomics*. 2009.

Distrusting consumers can hinder scientific advancement and care quality



Strong security protection, fair information practices, and "No Surprises" enable the learning health system to emerge



Risk to Personal Privacy

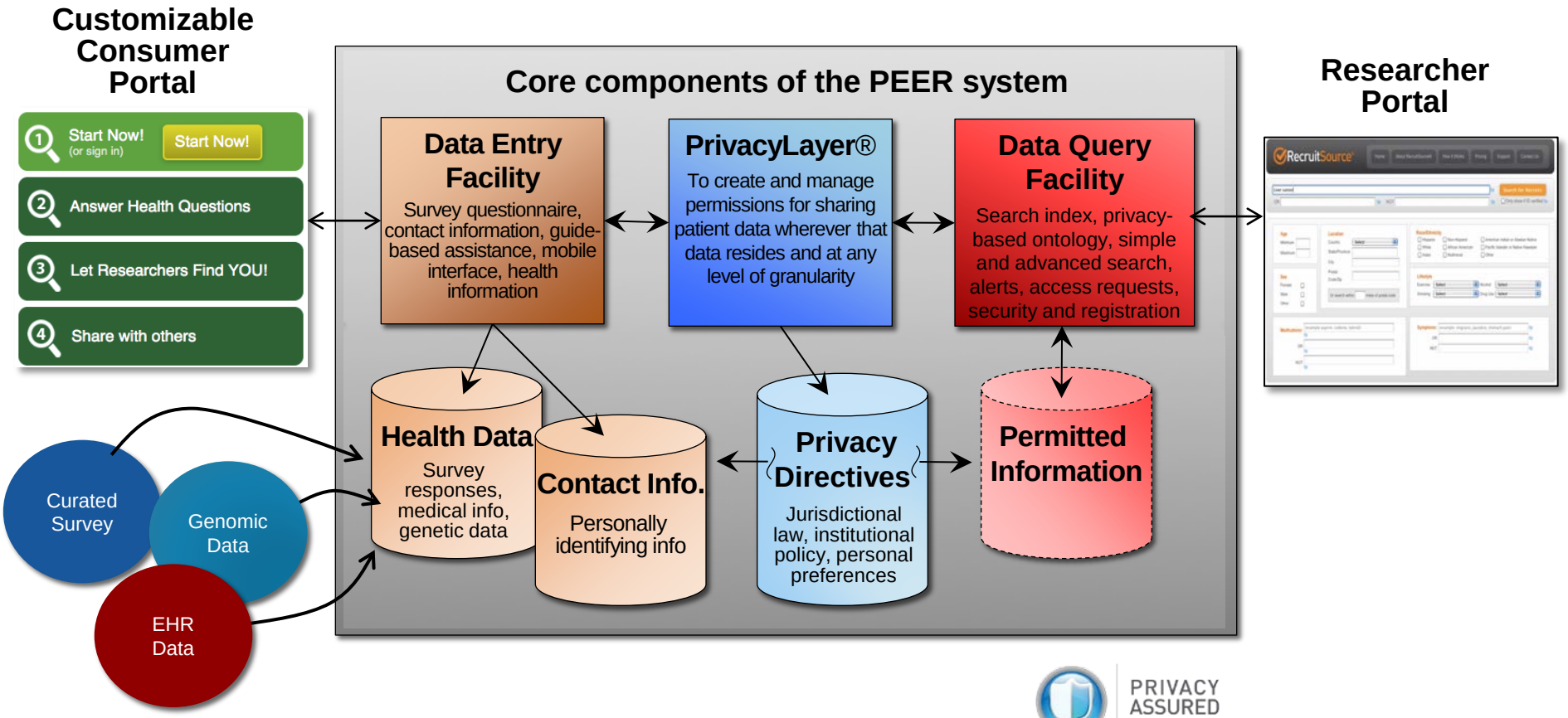
- DNA is inherently unique to the individual, rendering it the ideal "biometric identifier" – one of the 18 data elements of identifiability defined by HIPAA
- Even without a name or phenotype linkage, DNA includes many clues for narrowing the identity possibilities (e.g., presence/absence of Y chromosome reduces possibilities by around 50%)
- Genomic data are everywhere! DNA can be obtained from objects as ubiquitous as Starbuck's coffee cups
- Access to an individual's DNA poses a substantial privacy risk for both the individual and blood relatives (who most likely did not consent)
- Accelerating advances in genetic and "big data" technologies challenge the presumption that any health data can be "de-identified"

Genetic Alliance: Empowering Consumers to Help Meet the Research Challenge

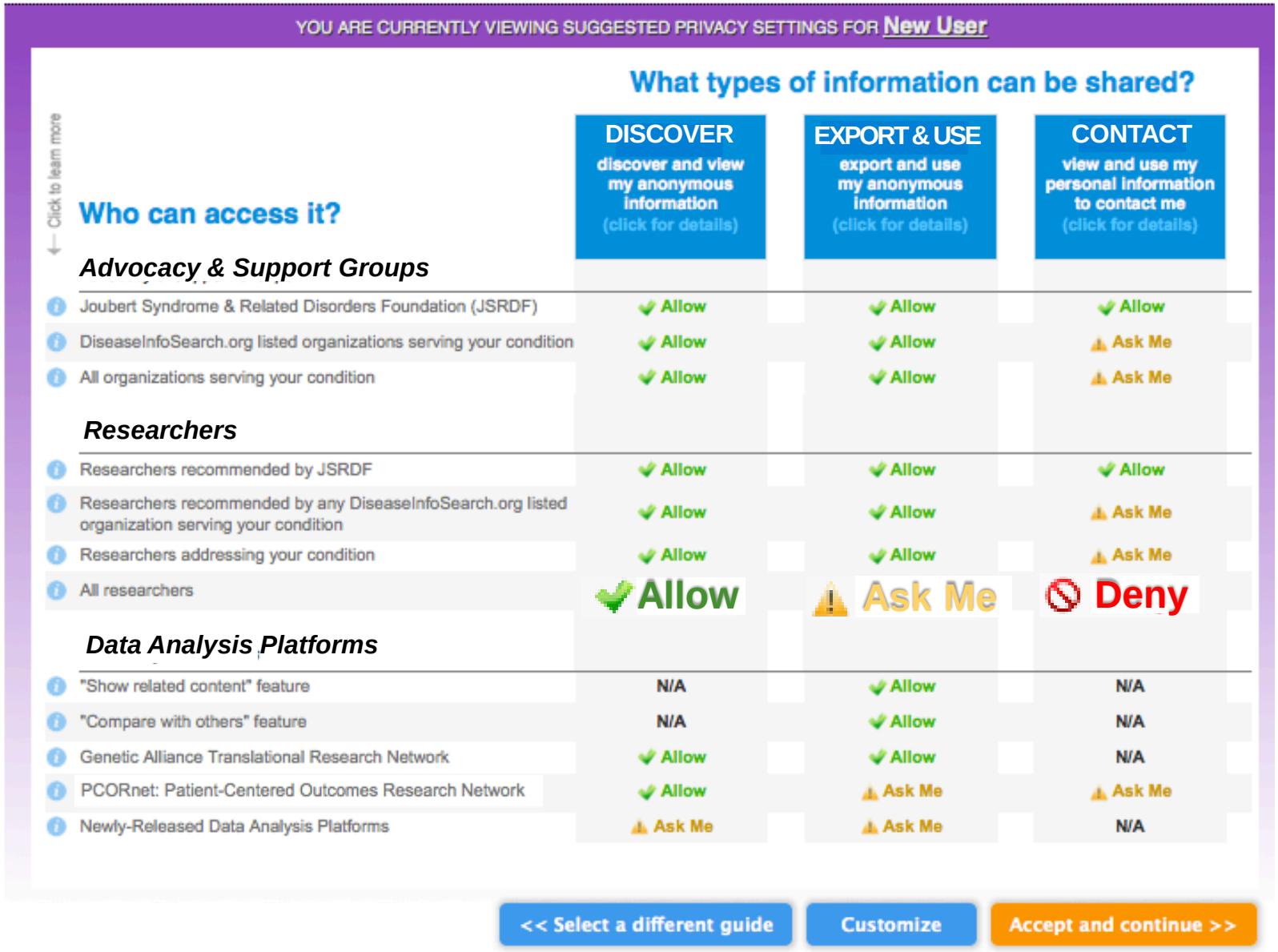
- Access to personal data to help advance biomedical research is most effectively enabled by gaining the trust and engagement of the individuals to whom the data pertain
- Through the use of powerful consent-management tools developed by Private Access, Genetic Alliance has developed a truly participant-centric research platform that enables individuals to make their health information available to researchers – under their own terms
- This highly flexible and customizable platform is called **Platform for Engaging Everyone Responsibly (PEER)**

PEER Logical Components and External Interfaces

PEER provides tools to customize the consumer portal and the researcher portal, including selection of guides and curation of questions, along with administrative tools to help host organizations manage their PEER site



Participants establish their own sharing preferences based on simple "stop-light" metaphor – Allow, Deny or Ask Me



Consumer-selected “guides” help individuals set their sharing preferences

Set Privacy Settings : For New User

Nicole Ford’s suggested privacy settings for persons with : Moderate concerns about privacy

1. Use the above selected level or choose a level of concern about privacy that more closely reflects your views.
2. If you are satisfied with Nicole’s suggested privacy settings shown below, click “Accept and continue”.
3. If not, either click “Customize” to refine these settings, or choose “Select a different guide”.

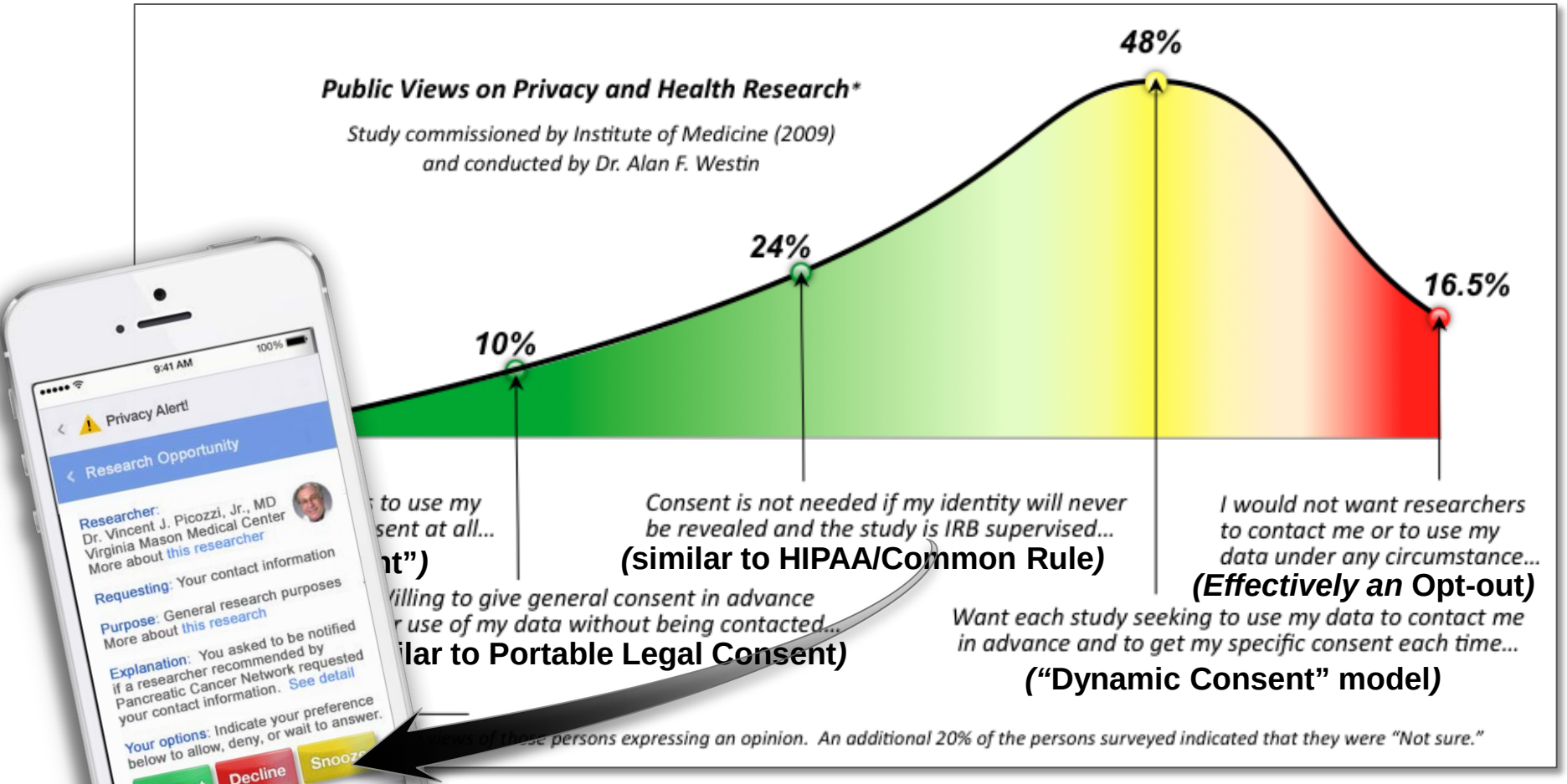
<< Select a different guide | Customize | Accept and continue >>

YOU ARE CURRENTLY VIEWING SUGGESTED PRIVACY SETTINGS FOR New User

← Click to learn more

Who can access it?	What types of information can be shared? DISCOVER discover and view my anonymous information (click for details)	EXPORT & USE export and use my anonymous information (click for details)	CONTACT view and use my personal information to contact me (click for details)
Advocacy & Support Groups			
Joubert Syndrome & Related Disorders Foundation (JSRDF)	Allow	Allow	Allow
DiseaseInfoSearch.org listed organizations serving your condition	Allow	Allow	Ask Me
All organizations serving your condition	Allow	Allow	Ask Me
Researchers			
Researchers recommended by JSRDF	Allow	Allow	Allow
Researchers recommended by any DiseaseInfoSearch.org listed organization serving your condition	Allow	Allow	Ask Me
Researchers addressing your condition	Allow	Allow	Ask Me
All researchers	Allow	Ask Me	Deny

PEER enables the expression of the full spectrum of personal views about privacy and sharing of health information



... with the ability to adjust settings dynamically as values and priorities change over time

Customizable PEER Entry Points Are Easily Embedded into Any Web Site

- Fully customize for any website
- Embeds gamified health survey
- Embeds PrivacyLayer® in each site
- Browser and tablet-based app
- Fully-integrated stats package

MIT Technology Review

New Disease Registry Gives Patients Some Privacy

A new venture lets patients choose how their data is used for medical research and offers sophisticated privacy settings.

By Courtney Humphries on March 14, 2013

PEER / PEER Mobile

EXAMPLES: https://www.reg4all.org, https://www.free-the-data.org, https://www.trialsfinder.org, http://sicklecellwarriors.com, http://www.umdf.org/site/c.8qKOJ0MvF7LUG/b.9135169/k.D604/Registry.htm

RESEARCHER PORTAL: https://www.recruitsource.com/Pages/Home.aspx

For More Information

- Genetic Alliance – PEER
  - http://www.geneticalliance.org/programs/biotrust/peer
- Community Engaged Network for All (CENA) – Patient Centered Outcomes Research Institute (PCORI) Patient Powered Research Network (PPRN)
  - http://www.geneticalliance.org/programs/biotrust/cena
- Dixie.Baker@martin-blanck.com