Patients' Perspectives on Human Participant Engagement in Cancer Research

National Cancer Policy Forum Workshop
Institute of Medicine

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Genetic Alliance

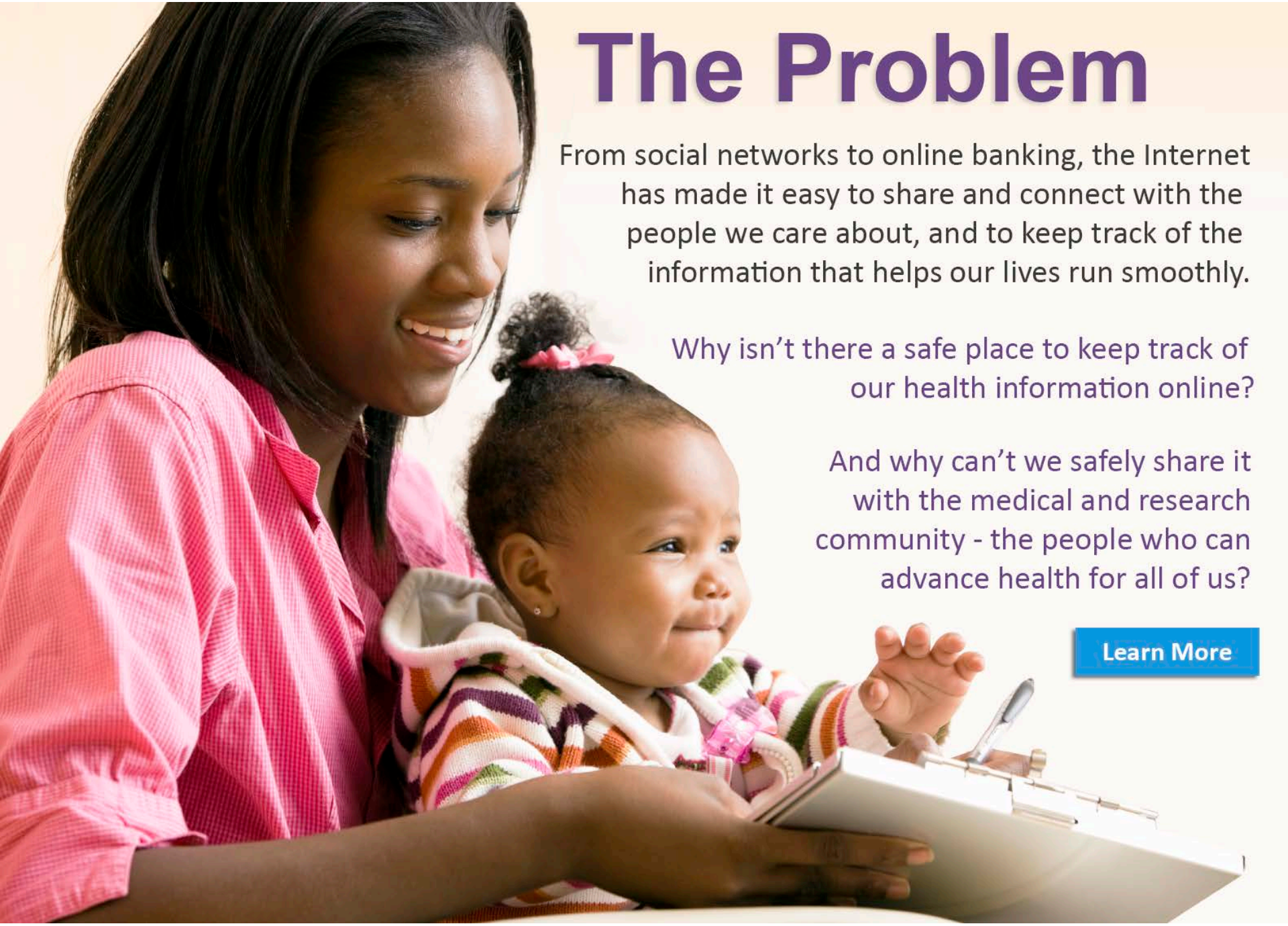
- Engage
- Relational/trust
- Contextual
- Share phenotypic data over time
- Determine outcomes (PCOR)
- Receive reports
- Viral communications
- Greater participation

Participant-centric path

- Avoid the person
- Transactional
- One size fits all
- Create solutions based on institutional needs
- Lose engagement
- Lose phenotypic data
- Lose longitudinal data
- Lose ability to report back

Researcher/institutional path

A highly regulated cottage industry



The Problem

From social networks to online banking, the Internet has made it easy to share and connect with the people we care about, and to keep track of the information that helps our lives run smoothly.

Why isn't there a safe place to keep track of our health information online?

And why can't we safely share it with the medical and research community - the people who can advance health for all of us?

Learn More

Needles in Haystacks

The haystack is made of needles...

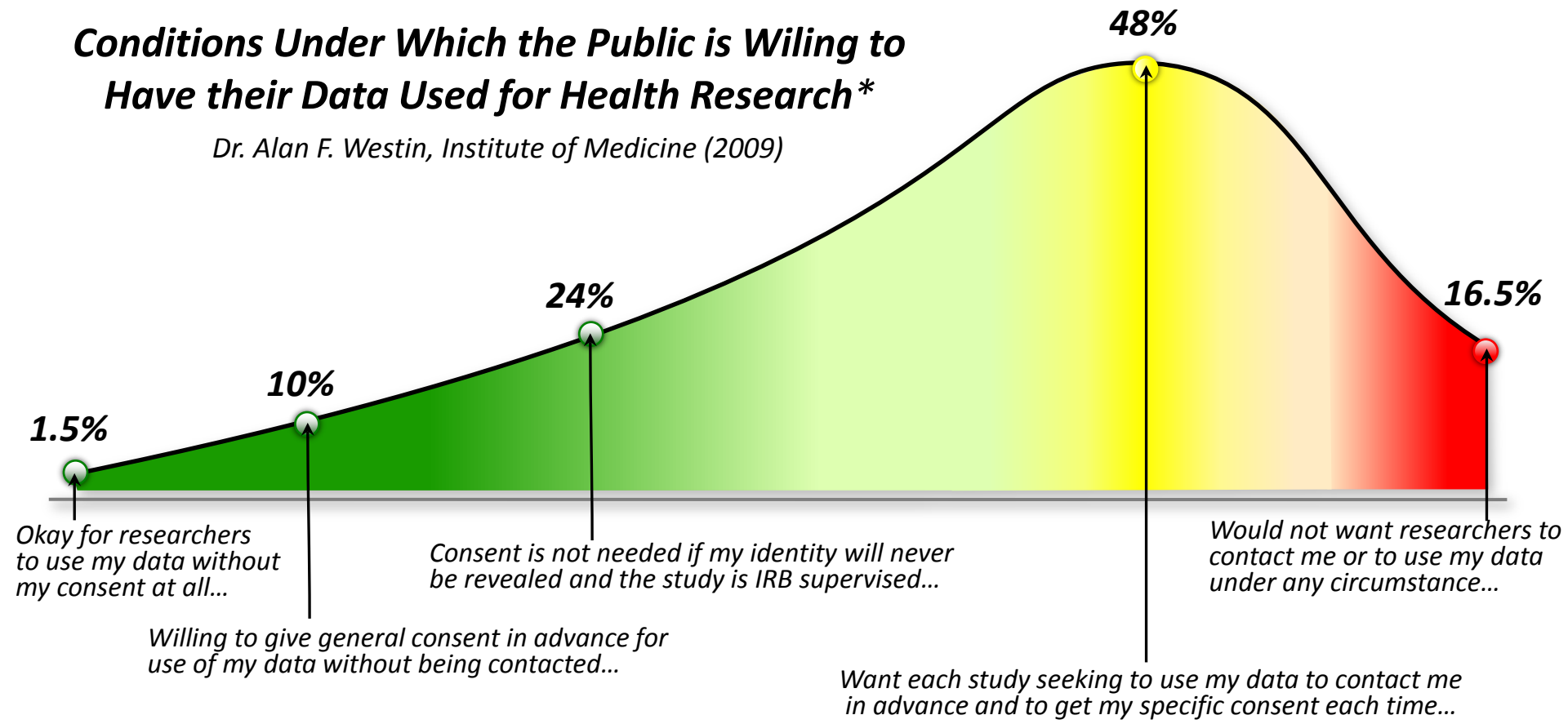
Culture Shift

Industrial Age	→	**Information Age**
Control means of production		**Open** means of production
Based on **scarcity**		Based on **abundance**
Hierarchical / Command		**Network** / Collaboration
Linear / Sequential		**Organic**
Win / Lose		Win / Win
Materials		**Information**

but biomedical research and healthcare lag…

People have vastly different views about sharing

Virtually every article on Big Data, every policy body, every medical research project is looking for a solution to the question: *"How can we share the clinical and genetic data of millions of individuals and still respect their diverse wishes?"*



* Percentages shown reflect the views of those persons expressing an opinion. An additional 20% of the persons surveyed indicated that they were "Not sure."

Research Enterprise

Consent

Fair Information Practice Principles (FIPPs)*: The foundation for Tiger Team recommendations

*The Tiger Team used the formulation of the Fair Information Practice Principles (FIPPs) endorsed by the HIT Policy Committee and adopted by ONC in the *Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information.*
http://www.healthit.gov/sites/default/files/nationwide-ps-framework-5.pdf

A novel perspective about access to data…

Registries and biobanks can be*…

**** And commonly are***

Physician-centric

Condition-centric

Investigator-centric

Organization-centric

Institution-centric

Inquiry-centric

Network-centric

Organ or body part-centric

Data type-centric

Study-centric

Sponsor-centric

But we decided to try something totally new… bold, paradigm-shifting, and create a registry that is (that truly is)

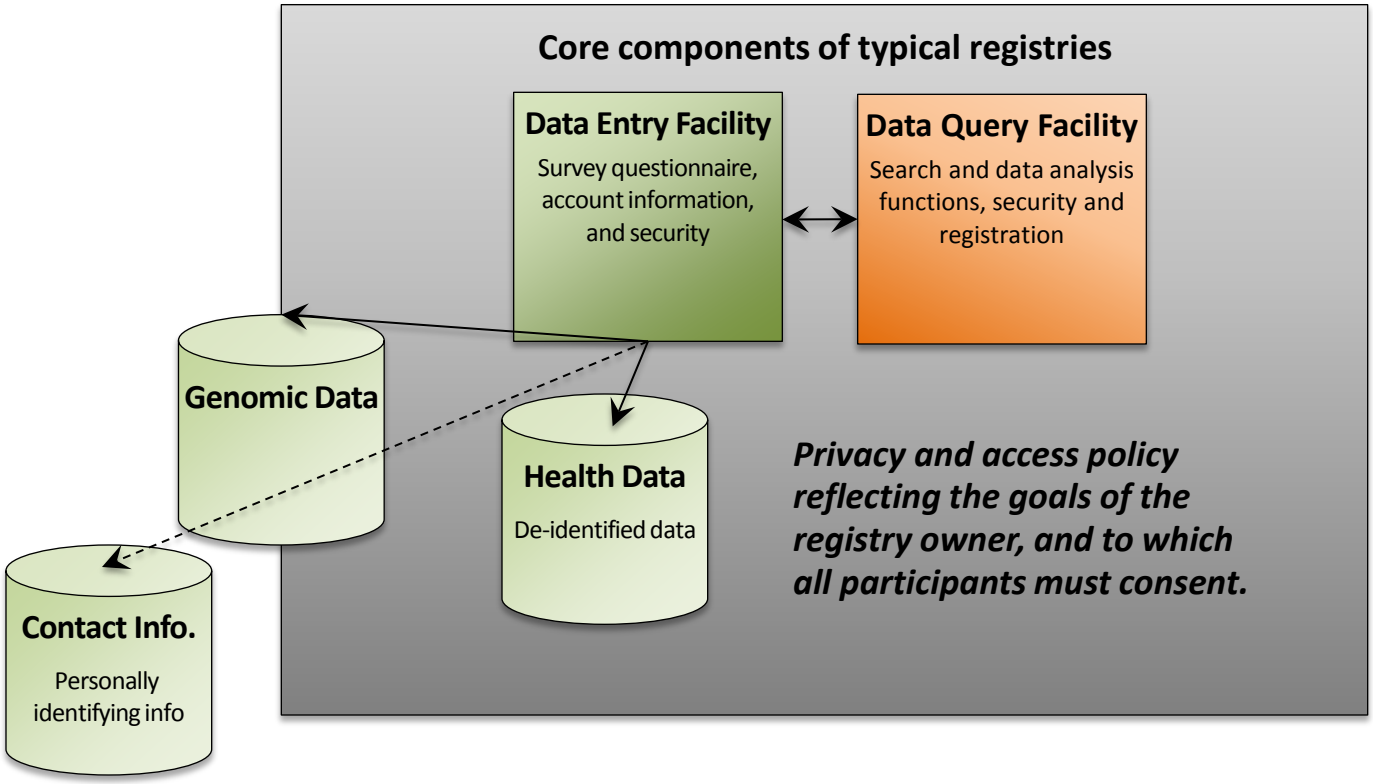
⋮

Participant-centric*

**** And not just in name only***

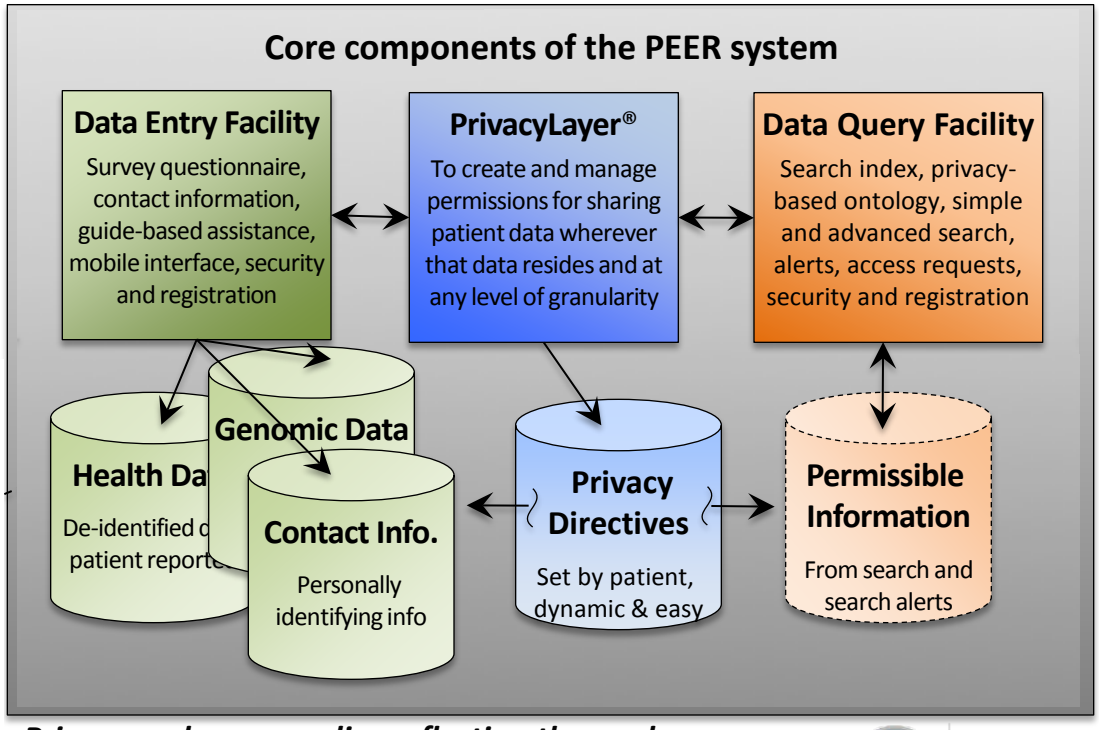
Typical Registry Architecture

Usual core components: functionality for data entry, a database of de-identified data, and facility for inquiry and/or analysis of that data based on the privacy and access policy of the registry owner to which all participants must consent in advance. Contact information for individual participants – if available – is most often loosely coupled, and outside the registry.



Platform for Engaging Everyone Responsibly (PEER)

PEER is participant-centric, adding a number of functions to the data entry facility and new privacy controls from Private Access that empower participants to create and manage access to all of their information. We move the contact details into the registry, with the right to access this data being separately managed by each participant.



Privacy and access policy reflecting the goal of PEER being participant-centric

PRIVACY ASSURED
with PrivateAccess

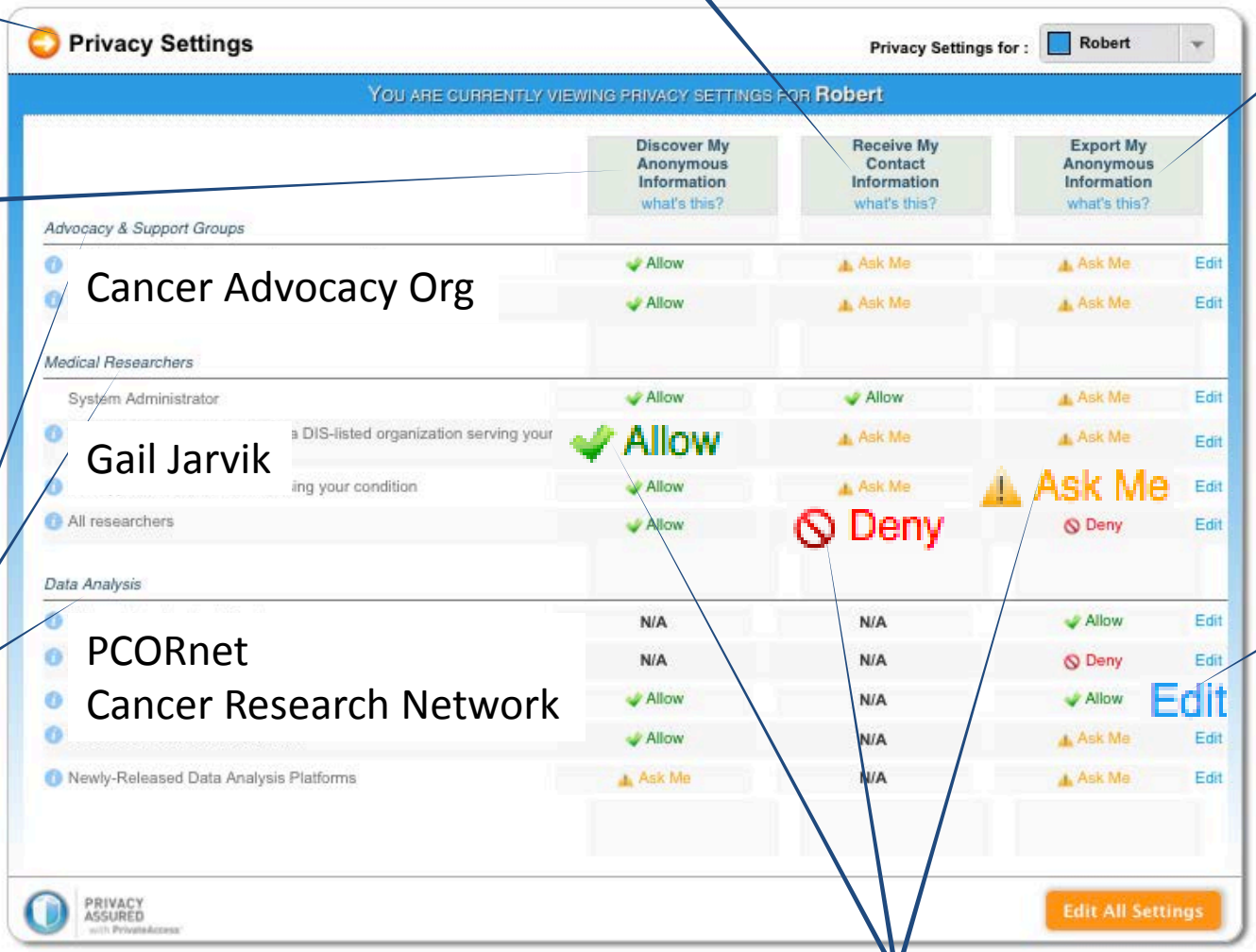
PEER enables a range of granular access controls, with ease

Participants use access controls to specify who can, and cannot, access or use their data, and for what purpose

"Contact Information" And separately, who can have access to their contact information

"Export" And who can export de-identified data from the PEER system

"Discovery" Each participant controls who can locate their de-identified data…



For multiple categories of uses, and specified usage rights

And given the option to Permit, Decline, or wait for more information before deciding

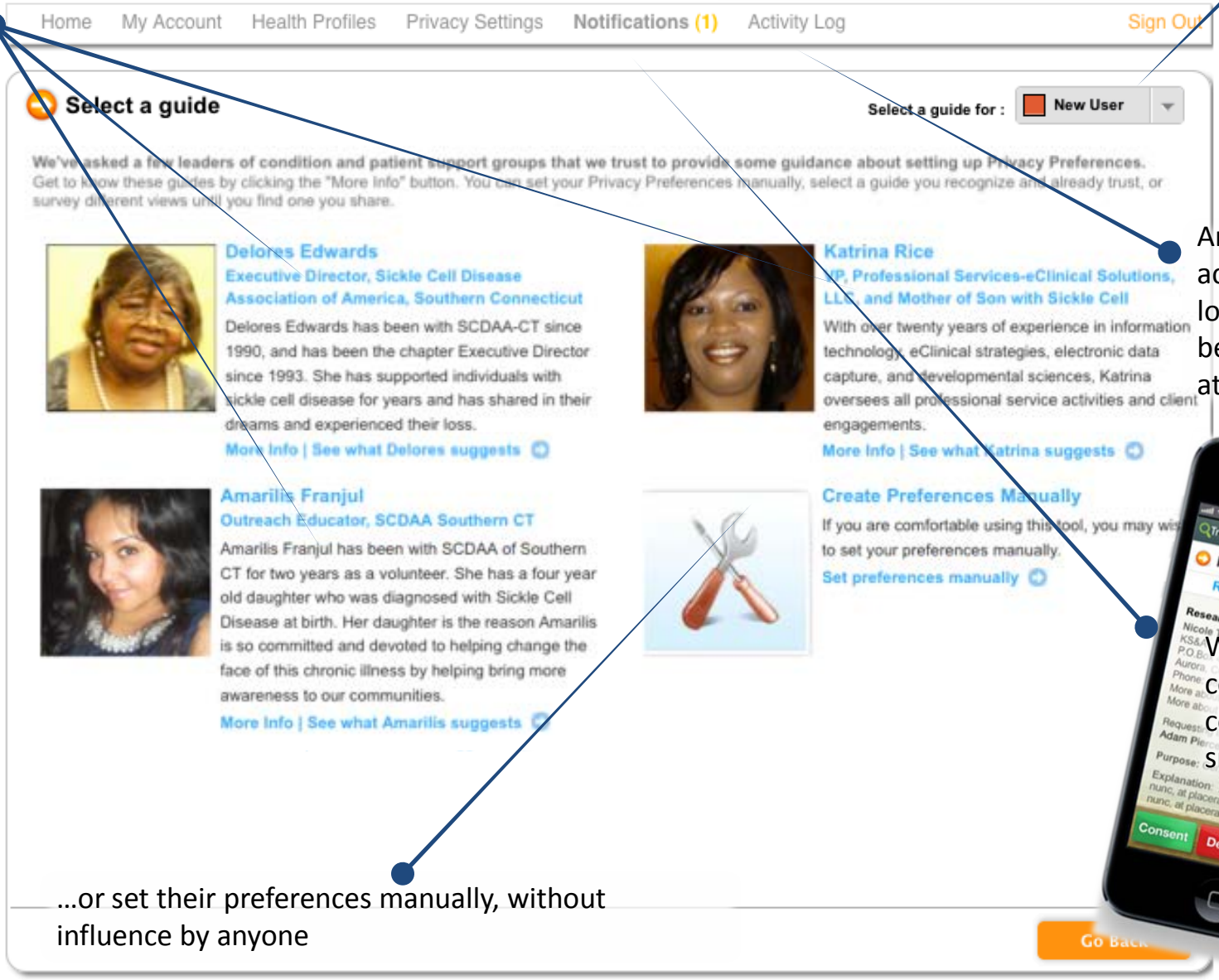
And the opportunity to change these preferences over time[1]

[1] *So long as the data is in PEER or a system that adheres to the person's Private Access settings.*

With a highly intuitive guide structure, notifications & dynamic consent

Knowledgeable community members - regarding data sharing and access controls

…for each member of their family, or use an existing group of settings as the basis for others



And with an easily accessible audit log for all activity being maintained at all times

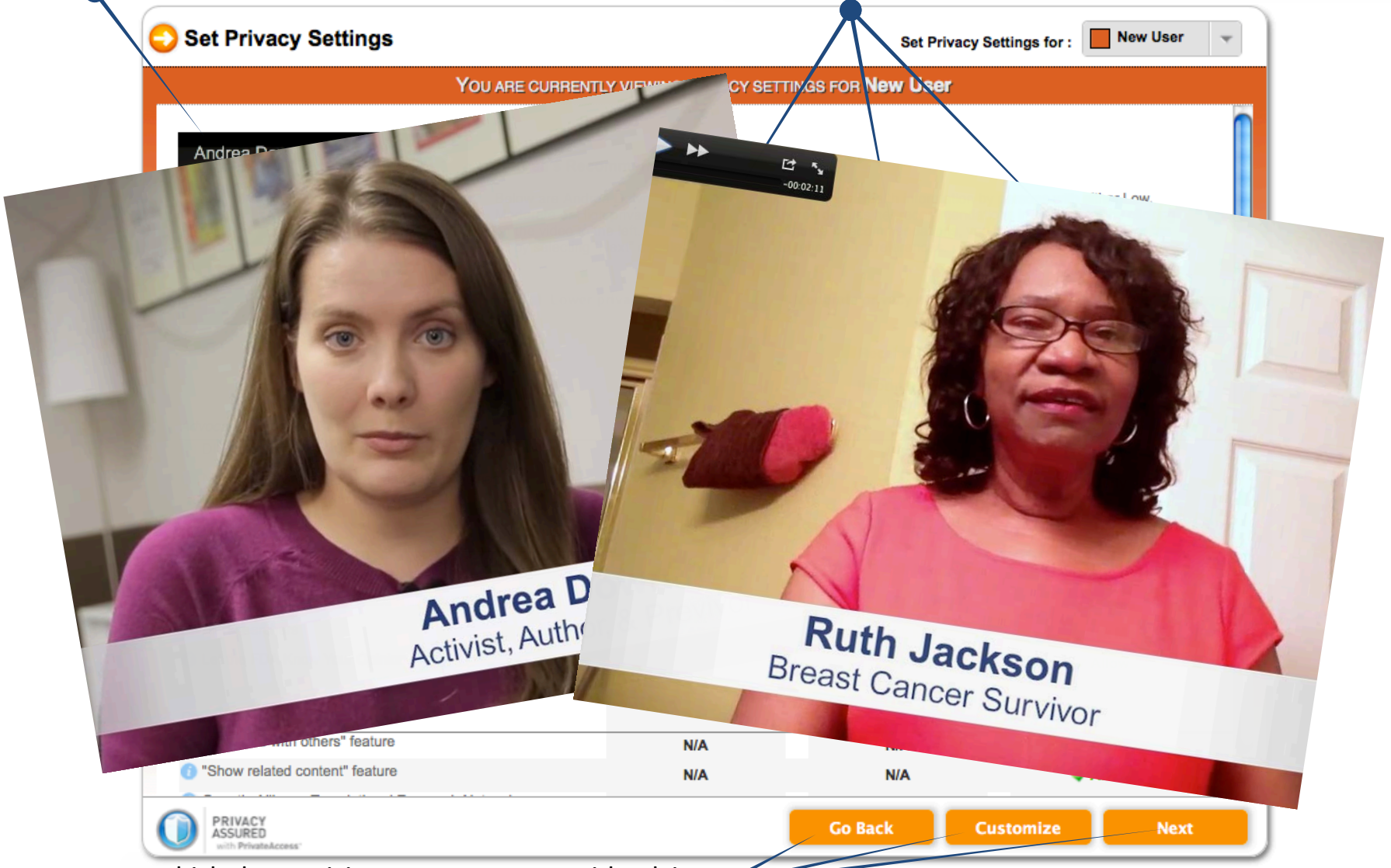
With dynamic consent from a computer or a smartphone

…or set their preferences manually, without influence by anyone

From my community, with knowledge and compassion

Each guide explains in their own words how they think about the issue and why it's important

And each guide suggests settings for people based on those participant's expressed level of concern regarding privacy

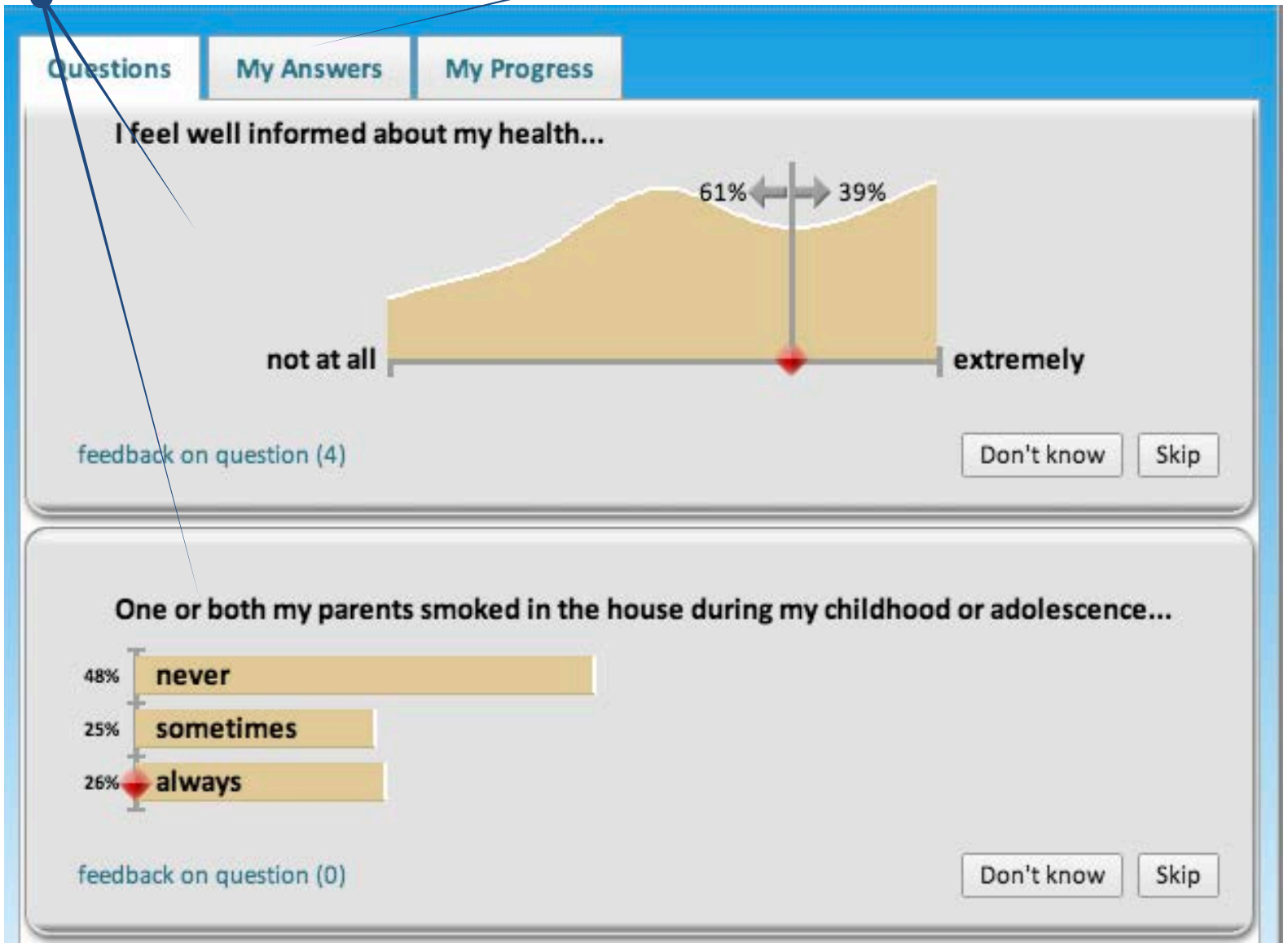


…which the participant can compare with advice from other guides, customize or accept and continue

With an engaging interface for questions and sponsorship opportunities

Questions appear in a dynamic user interface, and provide immediate feedback on how others responded to the same question…

And to review their prior answers, make updates and/or remove the data at any time.



Embed the PEER platform directly into any website

Useful on any website or blog

The group's selected logo art and call-to-action headlines and text appear fonts, background colors and links that express its theme

The opportunity to select from existing personalities or to substitute the group's leadership and key trusted members of its community

Flexibility to present the steps in the way the group feels will have the greatest appeal to its users

PEER network's unique participant-centric Privacy Policy and Terms of Use automatically extend to use on the site and are easily accessible

PEER provides a complete stats package to see what outreach strategies are working

The PEER portal can be placed in an iFrame directly onto the group's website

Each sponsor creates & manages from a single dashboard

Select and edit each element in the PEER portal to appear in the theme of its current website

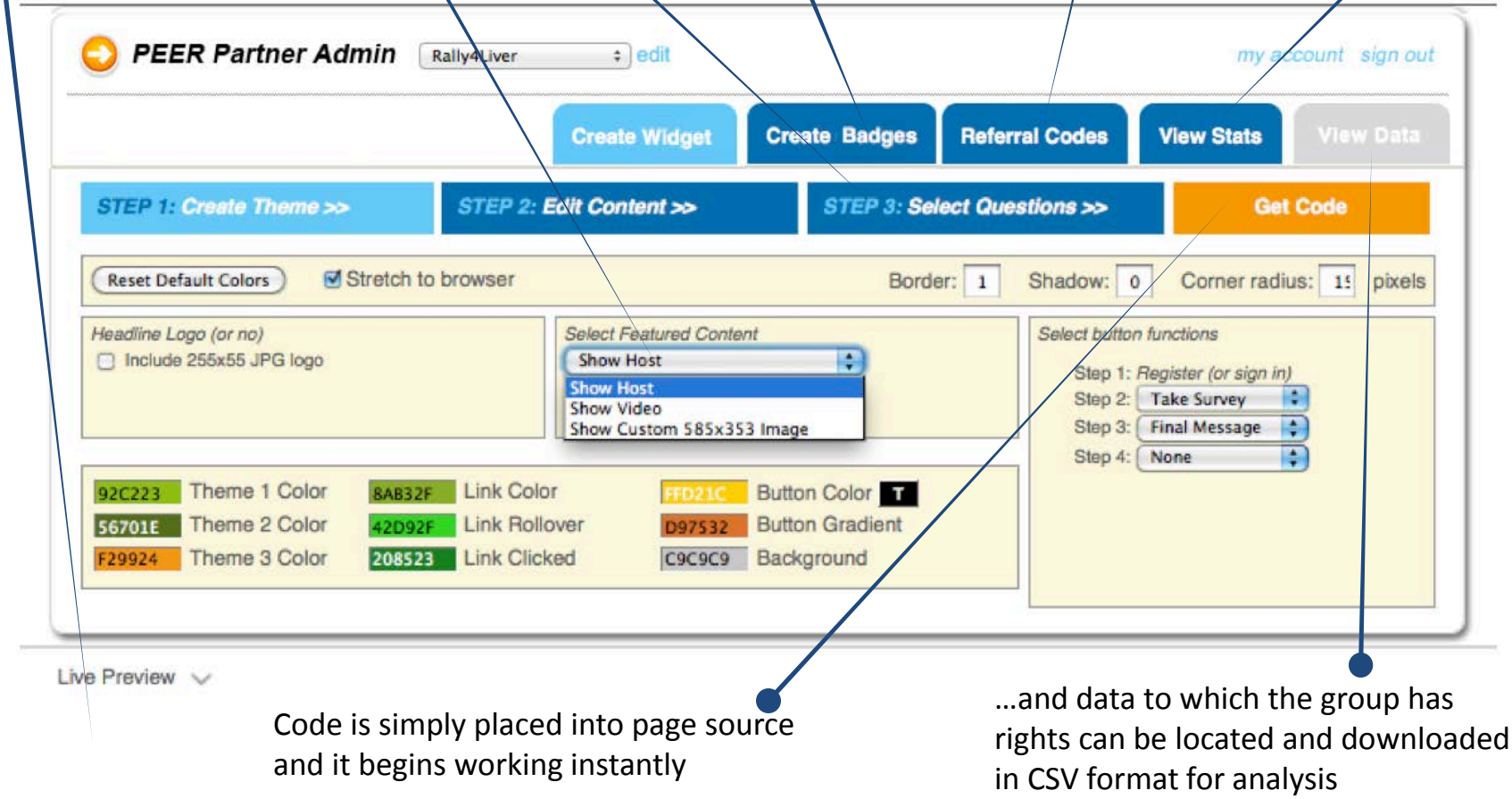
Curate inquiries (content, sequence, dependencies, etc) from a starting point of over 22,000 questions

Create referral codes to use on any printed communications like letters and posters

…and view a live preview of the page as it is modified

Also create custom badges to display on other websites

…and view statistics for how all of these assets perform and why



Code is simply placed into page source and it begins working instantly

…and data to which the group has rights can be located and downloaded in CSV format for analysis

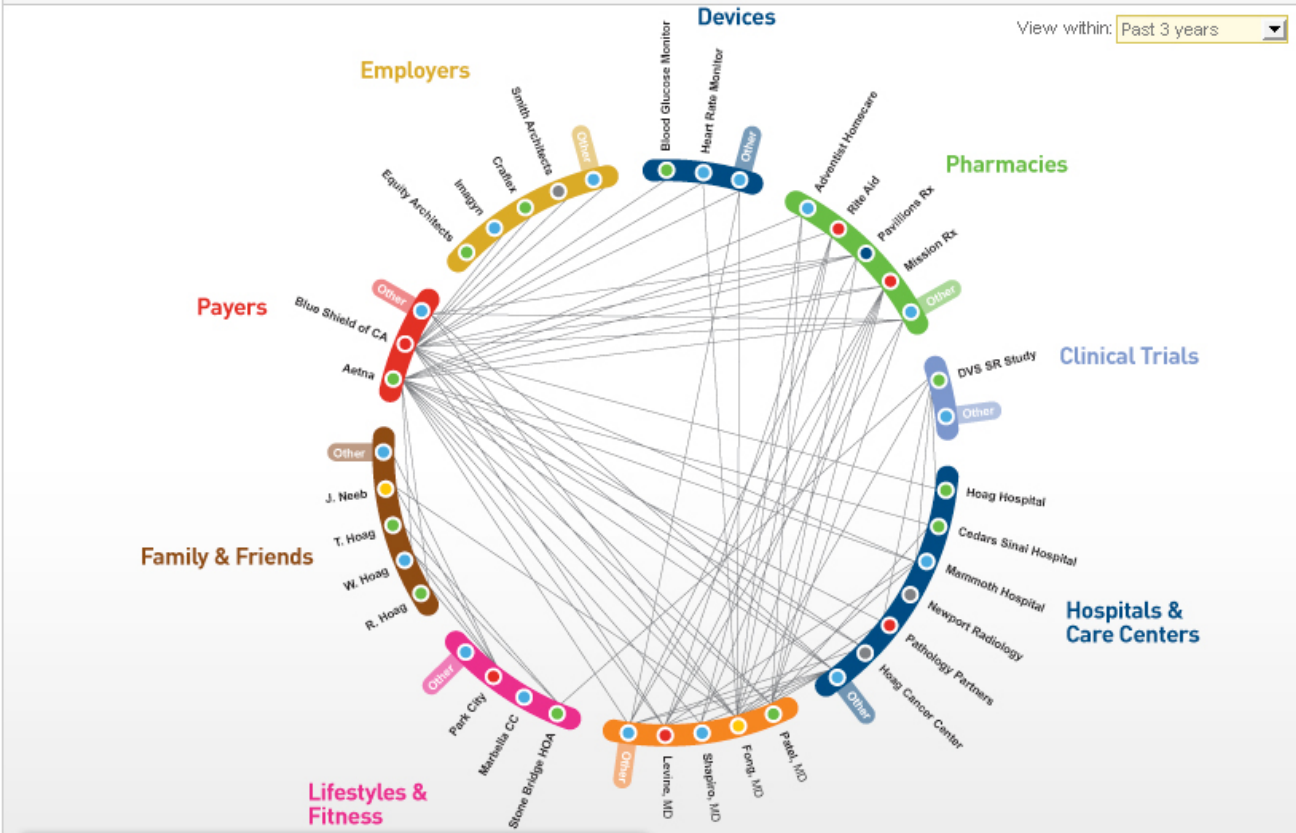
Your solution for controlling who sees your personal health information

Hello **Cassandra Hoag** (Sign Out)

PrivacyLayer™

Home | About PrivacyLayer | How it Works | Related Services | Support

Settings | My Health Universe | Privacy Concerns | New Opportunities



Control Panel ▸ Show

Legend ▸ Show

Introduction | Press | Partners | Careers | FAQs | Licensing Information | Privacy | Legal | Sitemap

HIPAA Covered Entities and PEER

In disseminating information about PEER, no covered entity is required to use or disclose PHI other than as permitted by HIPAA

Communicating to participants and their families options and services that could help meet their health needs is an important part of **case management** – PEER is such an option

PEER provides participants easy access to information about clinical trials that are investigating **treatment alternatives**

Case management and contacting patients with information about treatment alternatives are included in the HIPAA definition of **"health care operations"** (45 CFR §164.501)

A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations (45 CFR §164.506)

Individual Privacy Beyond HIPAA

- PEER is not a HIPAA covered entity; however, PEER affords individual participants a level of privacy protection that is beyond HIPAA

- PEER holds no personal information other than that which the participant or her representative explicitly provides, or requests that a third party provide – and the participant maintains continuous control over the use of her information

- Researchers using PEER to search for health information are able to discover and access information only as permitted by each participant
  - Participants may choose “permit,” “deny,” or “ask me later”
  - Participants may change their permissions at any time

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PEER Deployed

- **PCORnet – National Clinical Research Network awardee**

- **Patient Focused Drug Development (FDA PDUFA)**
  - Sickle Cell generic site:http://www.diseaseinfosearch.org/peer/sicklecell/
  - Citizens for Quality Sickle Cell Care:http://www.cqscc.org/index.php/how-to-help/national-sickle-cell-survey
  - North Alabama Sickle Cell Foundation:http://sicklecellna.org/peer.php
  - Sickle Cell Disease Association of America, Southern Connecticut: http://www.scdaaofsouthernct.org/tellthefda.html>
  - Sickle Cell Warriors: http://sicklecellwarriors.com/
  - The William E. Proudford Sickle Cell Fundhttp://www.wepsicklecell.org/tell-the-fda

- **Registries for All:** https://www.reg4all.org
- **TrialsFinder:** https://www.trialsfinder.org
- Free the Data: https://www.free-the-data.org

Credits:

- **Genetic Alliance**
  - Tanya Murza
  - Marybeth McAfee
  - Dean Suhr
  - **Dixie Baker**
- **Private Access**
  - **Robert Shelton**
  - Tom Hansen
- **UC San Francisco**
  - Mini Kahlon
- **UC Davis**
  - Nick Anderson

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