

Patients' Perspectives on Human Participant Engagement in Cancer Research

**National Cancer Policy Forum Workshop
Institute of Medicine**

February 24, 2014

Sharon F. Terry, President & CEO



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

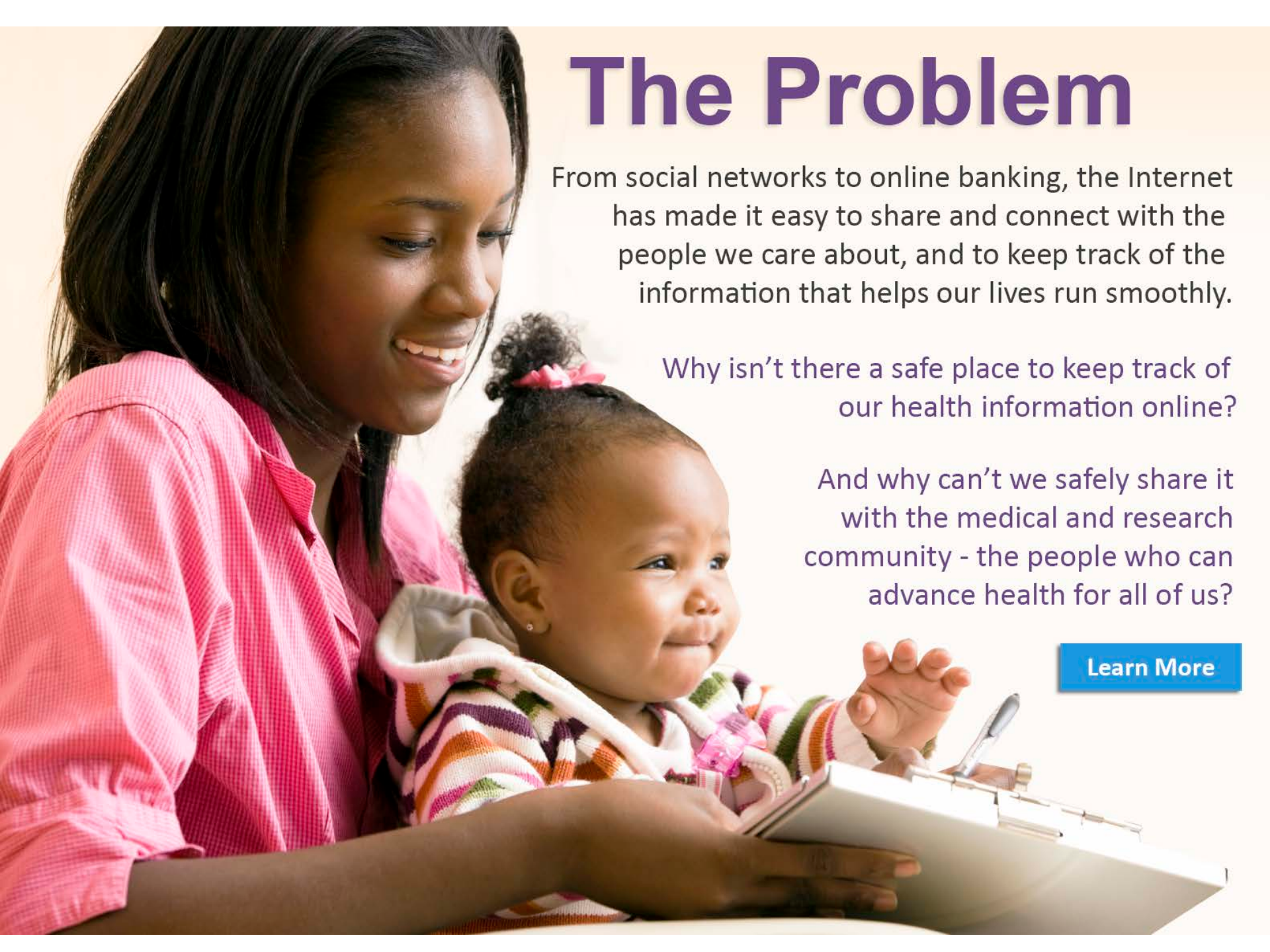
**Participant-centric
path**



- 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

Based on **scarcity**

Hierarchical / Command

Linear / Sequential

Win / Lose

Materials

Open means of production

Based on **abundance**

Network / Collaboration

Organic

Win / Win

Information

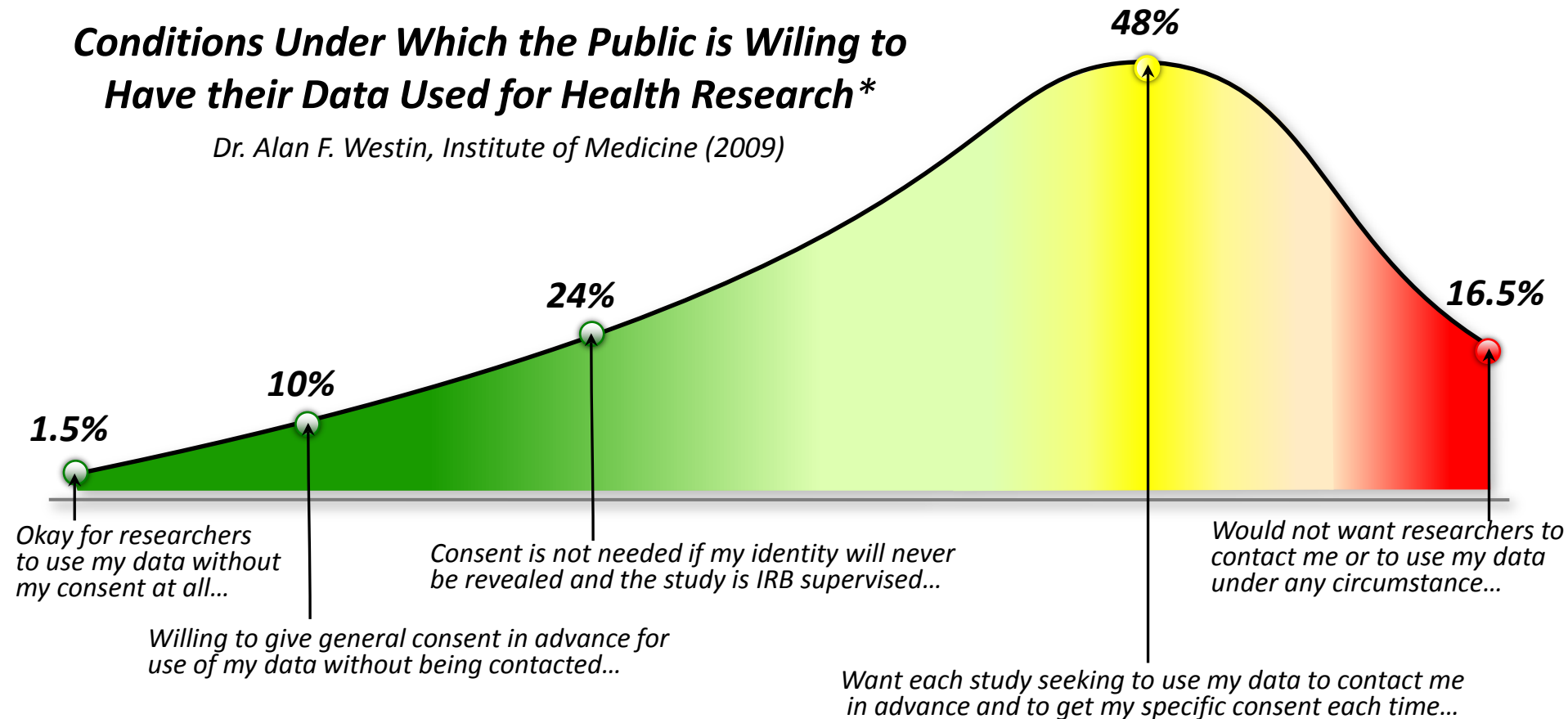
but biomedical research and healthcare lag...

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?”*

Conditions Under Which the Public is Wiling to Have their Data Used for Health Research*

Dr. Alan F. Westin, Institute of Medicine (2009)



* 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's
recommendations
are based on

Fair Information Practice Principles

Simple ways to get
Individual Access
to one's health information

ability to make a
Correction
to one's health information

Individual Choice
about how health information is used

Openness and Transparency
about policies, procedures, and technologies
that affect patients and their health information

health information is subject to
**Collection, Use and
Disclosure Limitations**

Safeguards
to ensure confidentiality
and control access

Data Quality and Integrity
of health information

Accountability
for adherence to these principles

*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

Data type-centric

Organ or body part-centric

Sponsor-centric

Study-centric

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

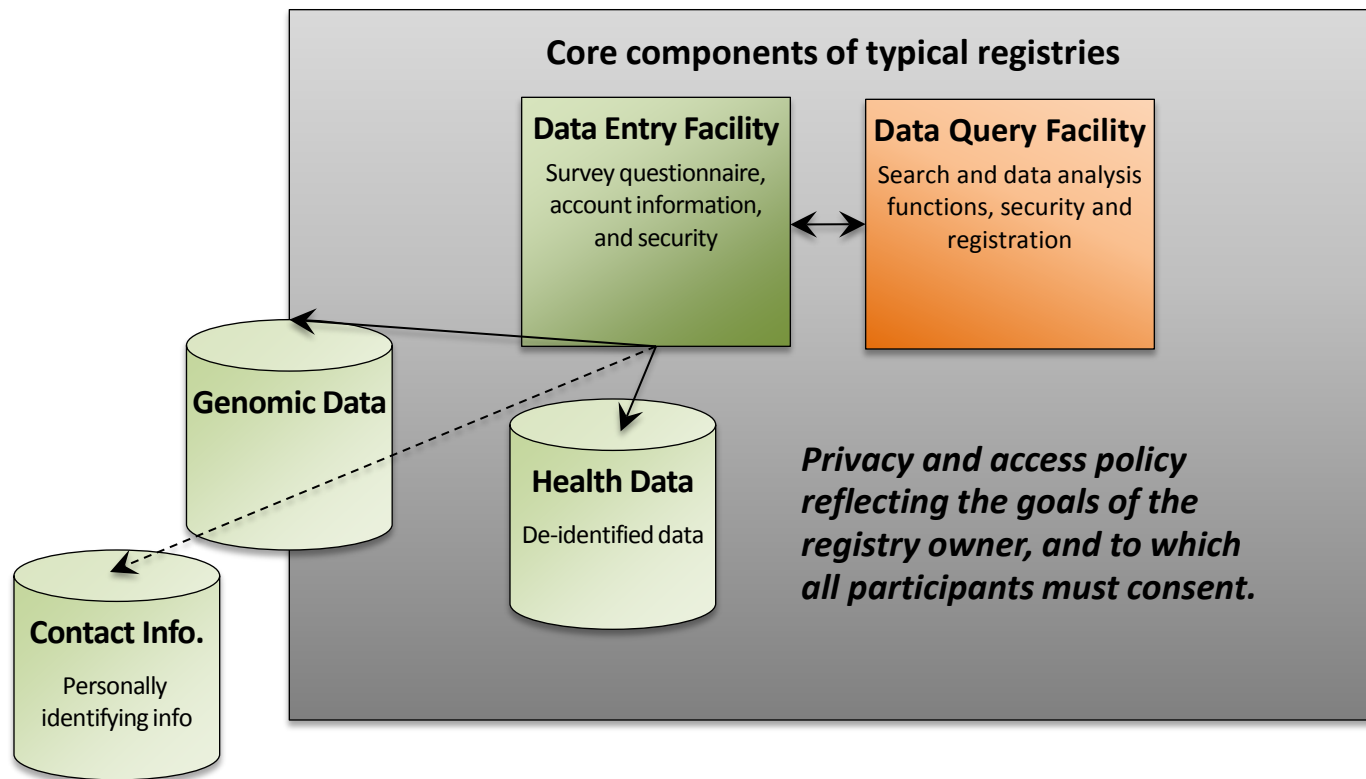


Participant-centric*

** And not just in name only*

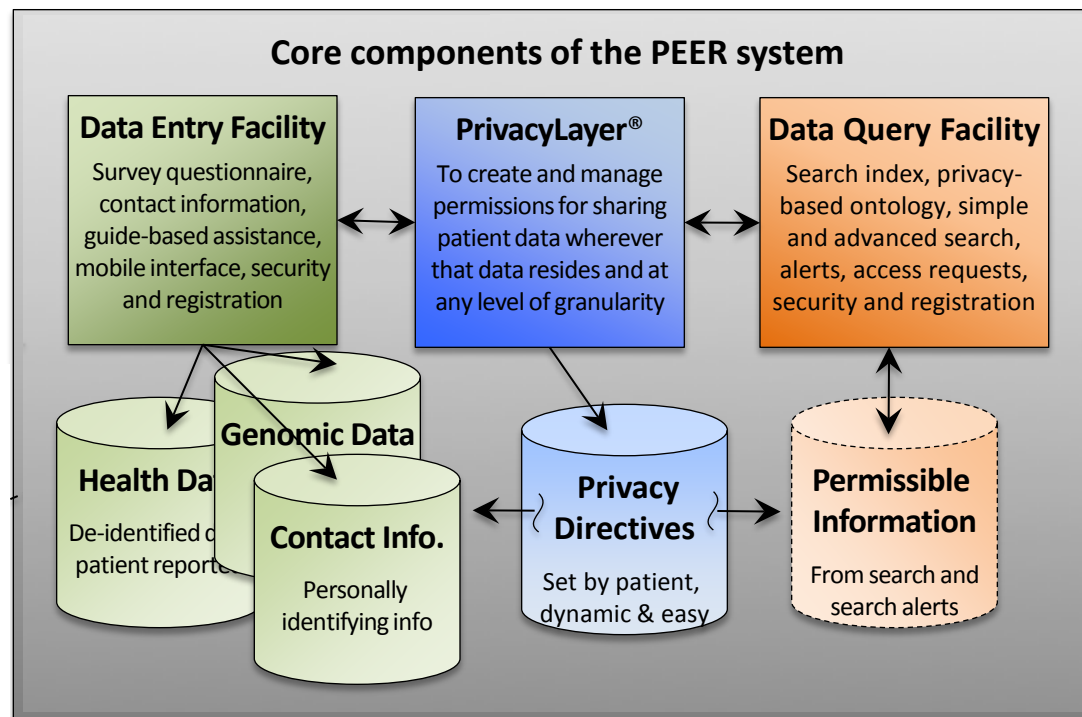
Typical Registry Architecture

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



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

Privacy Settings Privacy Settings for : Robert

YOU ARE CURRENTLY VIEWING PRIVACY SETTINGS FOR **Robert**

	Discover My Anonymous Information what's this?	Receive My Contact Information what's this?	Export My Anonymous Information what's this?
Advocacy & Support Groups			
Cancer Advocacy Org	Allow	Ask Me	Ask Me
	Allow	Ask Me	Ask Me
Medical Researchers			
System Administrator	Allow	Allow	Ask Me
Gail Jarvik	Allow	Ask Me	Ask Me
All researchers	Allow	Deny	Deny
Data Analysis			
PCORnet	N/A	N/A	Allow
Cancer Research Network	N/A	N/A	Deny
Newly-Released Data Analysis Platforms	Ask Me	N/A	Ask Me

PRIVACY ASSURED with PrivateAccess

Edit All Settings

And the opportunity to change these preferences over time¹

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

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

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

The screenshot shows a web application interface with a navigation bar at the top containing links: Home, My Account, Health Profiles, Privacy Settings, Notifications (1), Activity Log, and a Sign Out button. The main content area is titled "Select a guide" and includes a sub-header "Select a guide for : New User". Below this, a paragraph explains that the user can choose from guides provided by condition and patient support groups. Three guides are listed: Delores Edwards (Executive Director, SCDAA-CT), Katrina Rice (VP, Professional Services-eClinical Solutions, LLC, and Mother of Son with Sickle Cell), and Amarilis Franjul (Outreach Educator, SCDAA Southern CT). Each guide entry includes a profile picture, name, title, a brief bio, and links for "More Info" and "See what [Name] suggests". There is also a section titled "Create Preferences Manually" with a sub-header "Set preferences manually" and an icon of crossed wrench and screwdriver. A "Go Back" button is at the bottom right.

Home My Account Health Profiles Privacy Settings Notifications (1) Activity Log Sign Out

Select a guide

Select a guide for : New User

We've asked a few leaders of condition and patient support groups that we trust to provide some guidance about setting up Privacy Preferences. Get to know these guides by clicking the "More Info" button. You can set your Privacy Preferences manually, select a guide you recognize and already trust, or survey different views until you find one you share.

Delores Edwards
Executive Director, Sickle Cell Disease Association of America, Southern Connecticut
Delores Edwards has been with SCDAA-CT since 1990, and has been the chapter Executive Director since 1993. She has supported individuals with sickle cell disease for years and has shared in their dreams and experienced their loss.
[More Info](#) | [See what Delores suggests](#)

Katrina Rice
VP, Professional Services-eClinical Solutions, LLC, and Mother of Son with Sickle Cell
With over twenty years of experience in information technology, eClinical strategies, electronic data capture, and developmental sciences, Katrina oversees all professional service activities and client engagements.
[More Info](#) | [See what Katrina suggests](#)

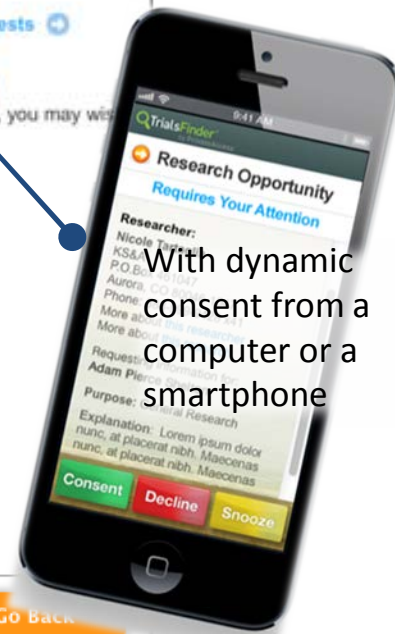
Amarilis Franjul
Outreach Educator, SCDAA Southern CT
Amarilis Franjul has been with SCDAA of Southern CT for two years as a volunteer. She has a four year old daughter who was diagnosed with Sickle Cell Disease at birth. Her daughter is the reason Amarilis is so committed and devoted to helping change the face of this chronic illness by helping bring more awareness to our communities.
[More Info](#) | [See what Amarilis suggests](#)

Create Preferences Manually
If you are comfortable using this tool, you may wish to set your preferences manually.
[Set preferences manually](#)

Go Back

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

With dynamic consent from a computer or a smartphone



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

The screenshot shows a web interface titled "Set Privacy Settings" for a "New User". The interface includes a header bar with the text "YOU ARE CURRENTLY VIEWING... CY SETTINGS FOR New User". Below the header, there are two video guides overlaid. The first guide, on the left, features a woman with long brown hair wearing a purple sweater, identified as "Andrea D. Activist, Author". The second guide, on the right, features a woman with short curly hair and glasses wearing a pink shirt, identified as "Ruth Jackson Breast Cancer Survivor". Below the video guides, there is a table with two columns: a feature name and a status. The first row shows "Show related content" feature with a status of "N/A". The second row shows "Show related content" feature with a status of "N/A". At the bottom of the interface, there is a "PRIVACY ASSURED with PrivateAccess" logo and three buttons: "Go Back", "Customize", and "Next".

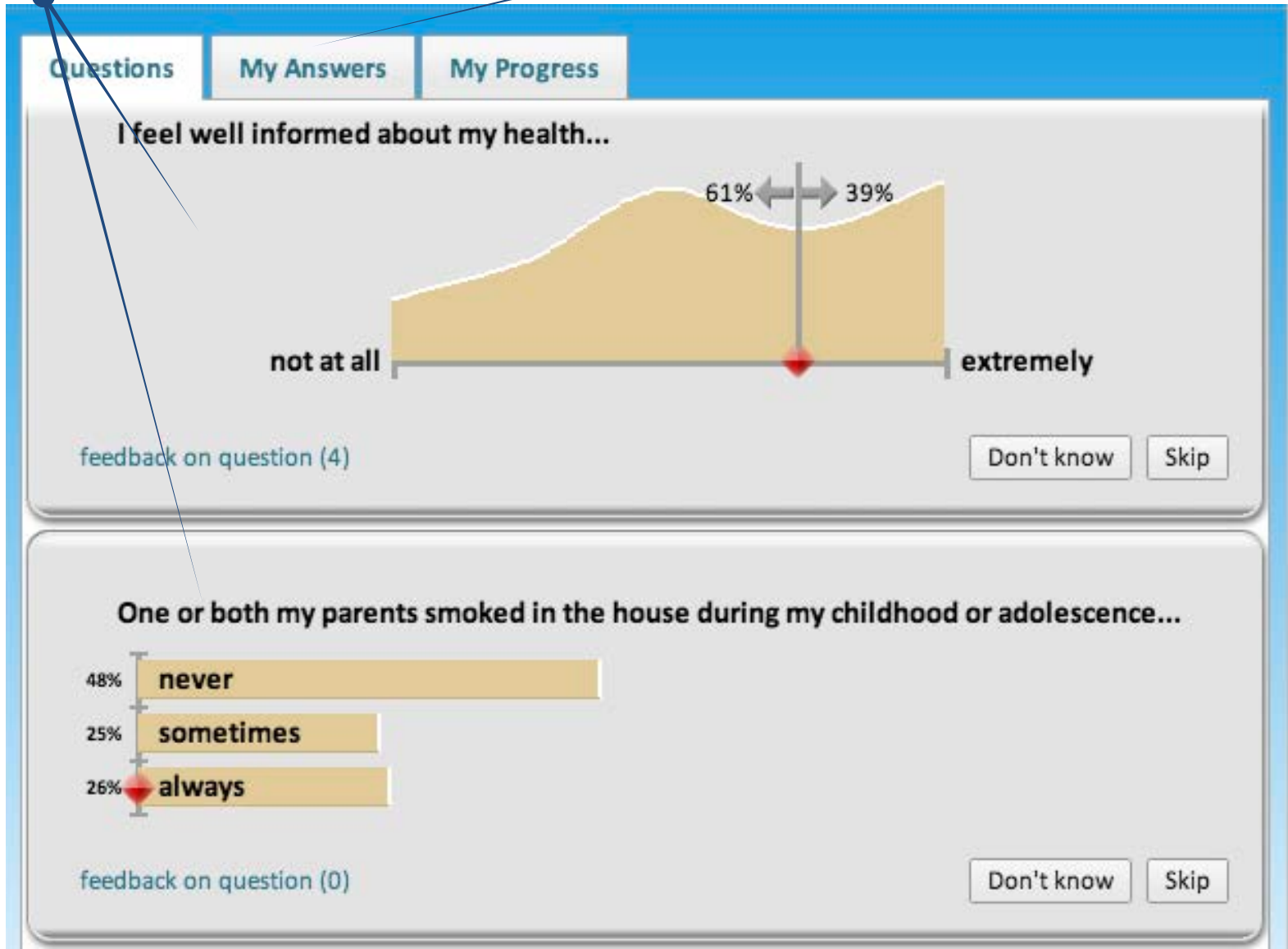
Feature	Status
"Show related content" feature	N/A
"Show related content" feature	N/A

...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

CITIZENS FOR QUALITY SICKLE CELL CARE
"Now we have a voice!"
©2014 Genetic Alliance, Inc.

Home | How We Use Our Voice! | **How to Help** | Calendar | Media | Resources | Contact Us

Let's tell the FDA how important it is to find a cure for Sickle Cell Disease

In February 2014, the Food & Drug Administration (FDA) will hold hearings into sickle cell disease, and it's critical your voice is heard there. This is our opportunity to tell the government about the needs and concerns of millions of Americans affected by sickle cell trait and disease. You can help just by answering a few questions; and if you want, you can also allow researchers to alert you about new studies for which you may qualify...[See how it works!](#)

“This is our chance to tell the FDA about the need for more drugs and therapies of people with Sickle Cell Disease”

Katrina Rice
44 year old mother of a child with Sickle Cell Disease

It's Easy as 1, 2, 3, 4

- 1 Protect your privacy **Start Now!**
- 2 Tell the FDA your opinion
- 3 Provide more health info
- 4 Help Spread The Word!

We Respect Your Right To Privacy

We understand that many people in our community have concerns about privacy. We are committed to protecting your right to decide how active and open to be. And that's why we're using Private Access to let you establish the rules for who can see your information, when, and for what purpose.

MY DOCTOR OR DISEASE ADVOCACY GROUP RECOMMENDED THIS SERVICE AND PROVIDED ME WITH A REFERRAL CODE:

Enter referral code here **Submit**

PRIVACY ASSURED

© 2013 Genetic Alliance, Inc. All rights reserved | [Privacy Policy](#) | [Terms of Service](#) | [Give Feedback](#)

Copyright © 2014 CQSCC-Citizens for Quality Sickle Cell Care. Designed by [atjoomla.com](#)

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

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

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

Also create custom badges to display on other websites

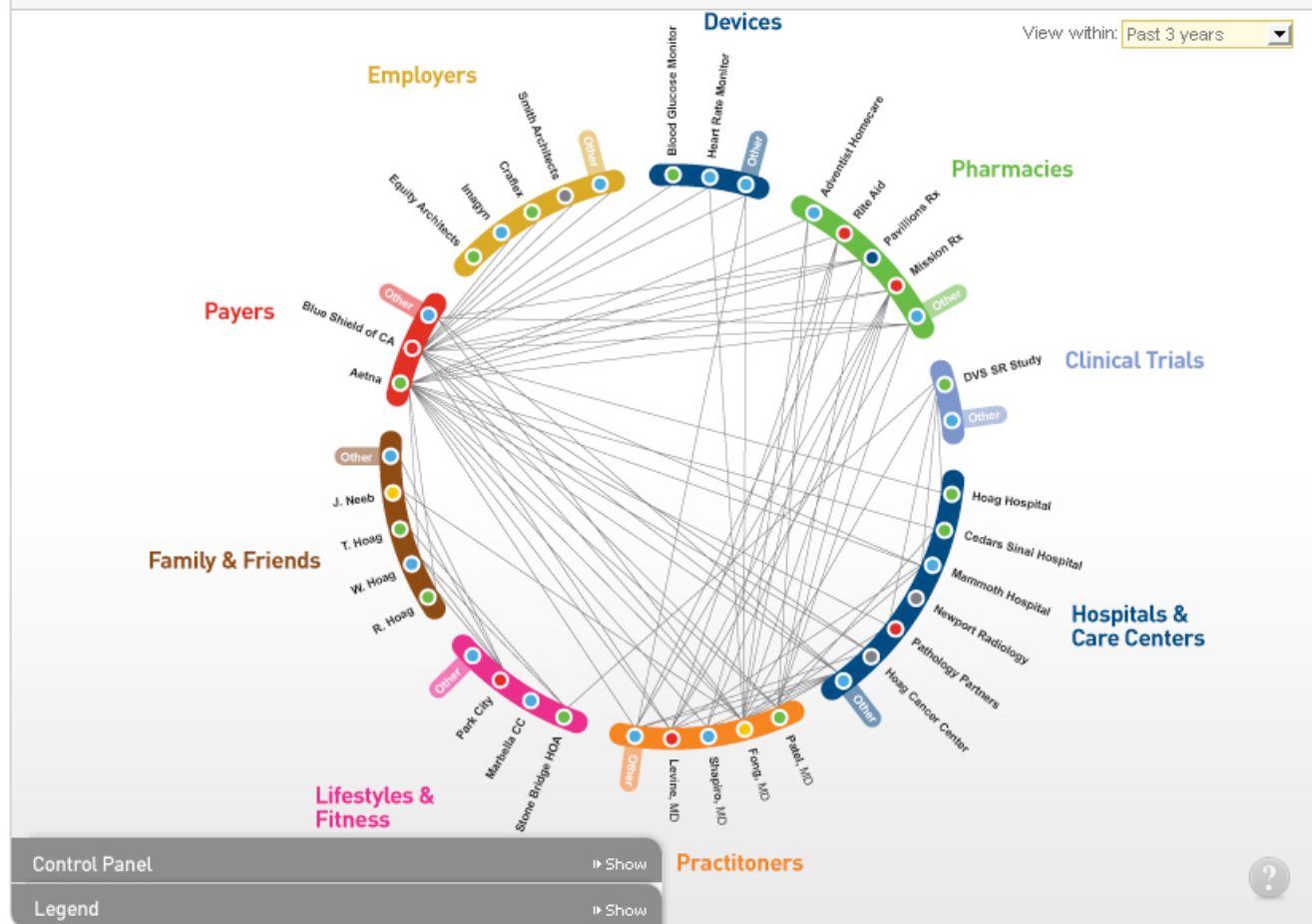
Create referral codes to use on any printed communications like letters and posters

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

The screenshot displays the 'PEER Partner Admin' interface for a user named 'Rally4Liver'. The top navigation bar includes links for 'my account' and 'sign out'. Below this is a row of buttons: 'Create Widget', 'Create Badges', 'Referral Codes', 'View Stats', and 'View Data'. The main content area is divided into four steps: 'STEP 1: Create Theme >>', 'STEP 2: Edit Content >>', 'STEP 3: Select Questions >>', and 'Get Code'. The 'Edit Content' step is active, showing options to 'Reset Default Colors' and 'Stretch to browser'. It also includes settings for 'Border', 'Shadow', and 'Corner radius'. The 'Select Featured Content' dropdown menu is open, showing options like 'Show Host', 'Show Video', and 'Show Custom 585x353 Image'. The 'Select button functions' section shows a sequence of steps: 'Step 1: Register (or sign in)', 'Step 2: Take Survey', 'Step 3: Final Message', and 'Step 4: None'. At the bottom, there is a 'Live Preview' button and a color palette with various theme and link colors.

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

[Home](#)[About PrivacyLayer](#)[How it Works](#)[Related Services](#)[Support](#)[Settings](#)[My Health Universe](#)[Privacy Concerns](#)[New Opportunities](#)

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**

```
graph TD; A[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] --> C[Case management and contacting patients with information about treatment alternatives are included in the HIPAA definition of health care operations (45 CFR §164.501)]; B[PEER provides participants easy access to information about clinical trials that are investigating treatment alternatives] --> C; C --> D[A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations (45 CFR §164.506)];
```

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

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

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.cqsgcc.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 Fund <http://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**
- **UC San Francisco**
 - Mini Kahlon
- **UC Davis**
 - Nick Anderson
- **Private Access**
 - **Robert Shelton**
 - Tom Hansen