Arizona Senate

SB 1258 Consent Amendment

Opt-in vs. Opt-out

Electronic Consent Solutions

Testimony of Deborah C. Peel, MD
Patient Privacy Rights
February 16, 2010

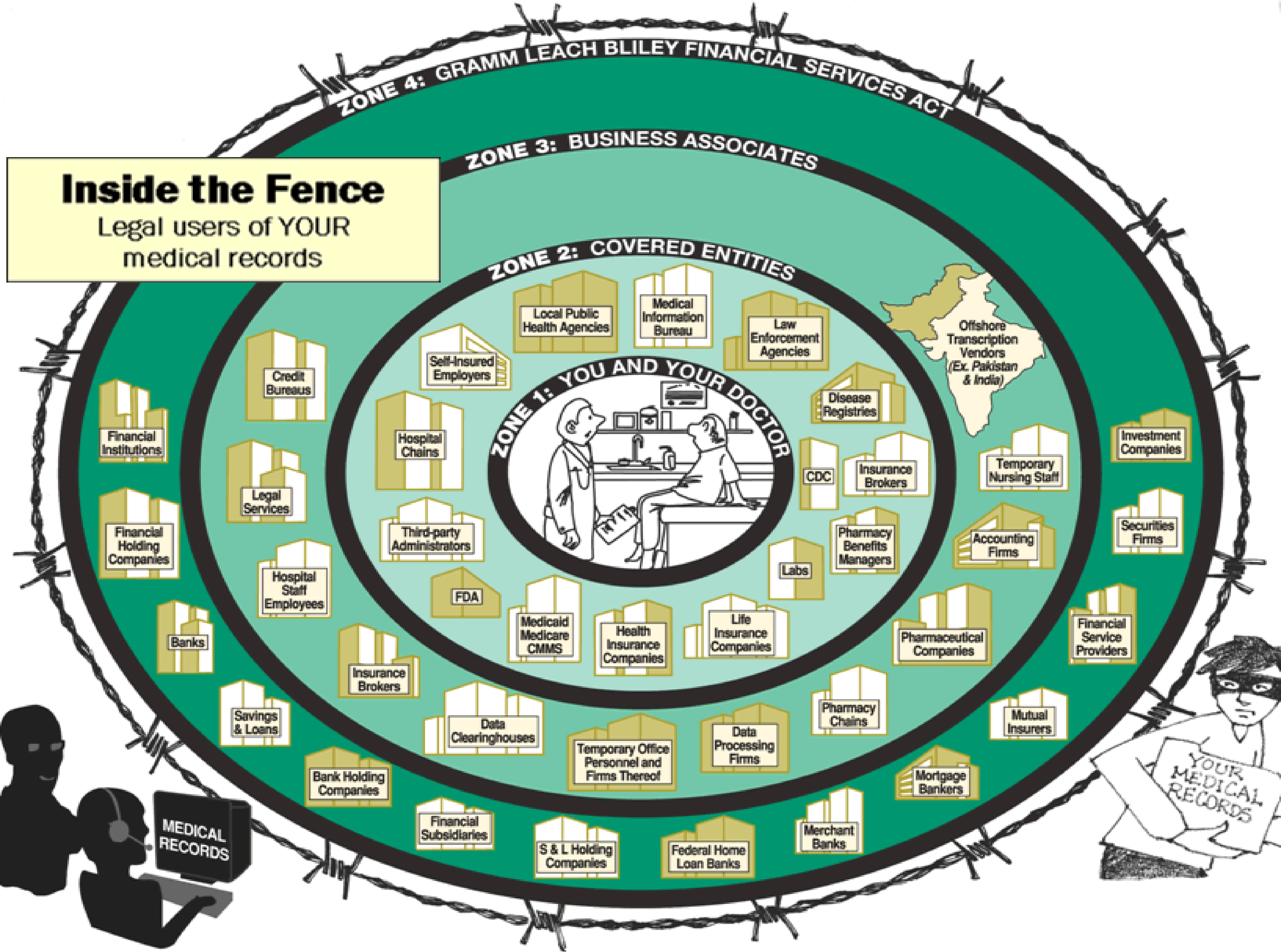
2,400 years of
consensus on privacy
reflected in American law,
medical ethics,
and professional standards
of practice

The Elimination of Consent

1996	Congress passed HIPAA, but did not pass a federal medical privacy statute, so the Dept. of Health and Human Services (HHS) was required to develop regulations to specify patients' rights to health privacy.	*"… the Secretary of Health and Human Services shall submit to [Congress]…**detailed recommendations on standards with respect to the privacy of individually identifiable health information."***
2001	President Bush implemented the HHS HIPAA "Privacy Rule" which recognized the "right of consent".	*"….a covered health care provider **must obtain the individual's consent,** in accordance with this section, prior to using or disclosing protected health information to carry out treatment, payment, or health care operations."*
2002	HHS amended the HIPAA "Privacy Rule", eliminating the "right of consent".	*"The **consent provisions…are replaced** with a new provision…that provides regulatory permission for covered entities to use and disclose protected health information for treatment, payment, healthcare operations."*

Inside the Fence

Legal users of YOUR medical records



Arizonans' Perceptions About Health Information Technology 2009 Healthcare Consumer Focus Group Findings

Arizona Health-e Connection
Issue Paper

DRAFT

Arizona
Health-e
Connection
www.azhec.org

Advancing health and wellness through information technology

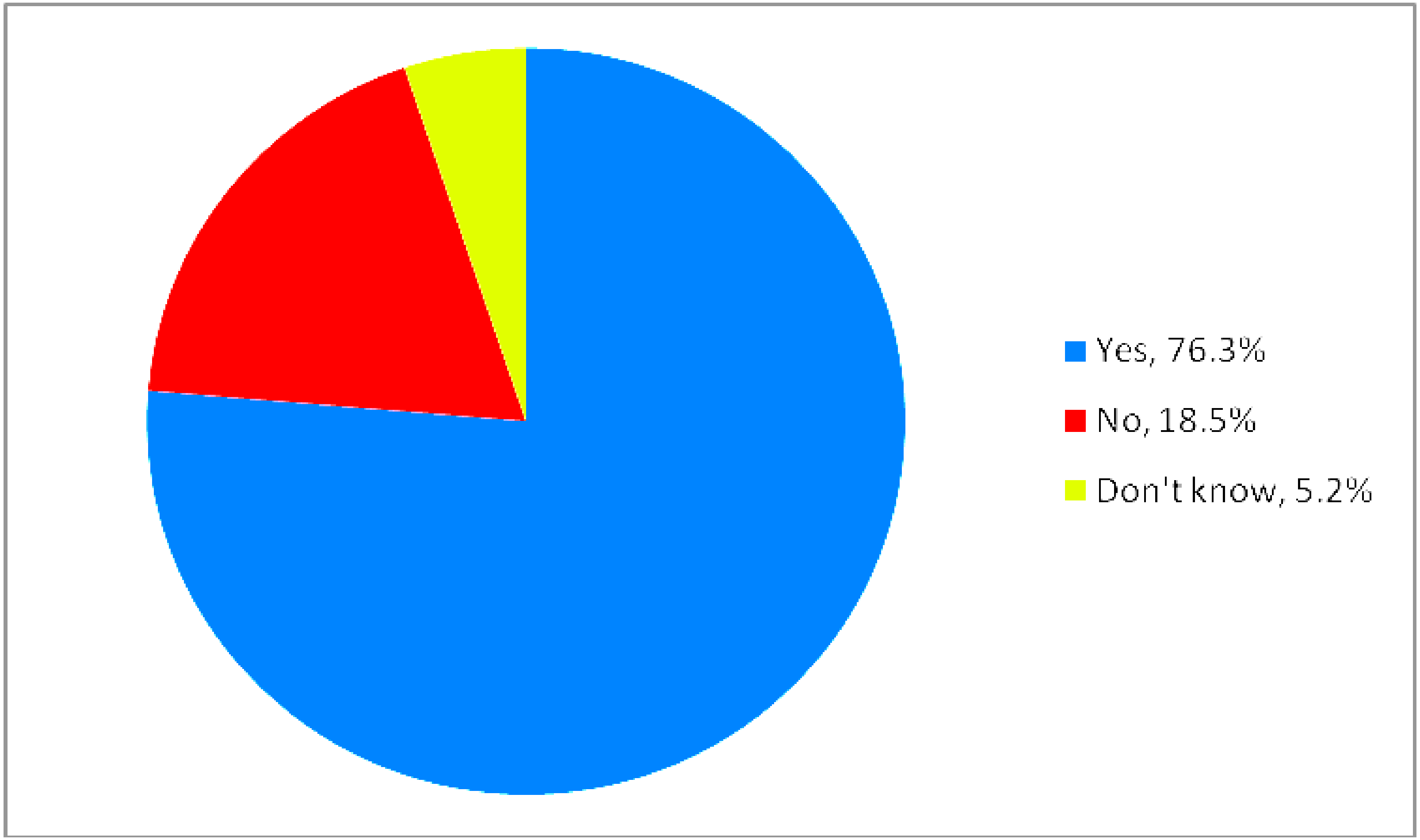
8 Focus groups/ 177 people

April 29 - June 17, 2009

Surprise
San Luis/Yuma (2)
Marana/Tucson
Arizona State University (2)
Flagstaff
Tempe

Statistical error rate of ±6.2 %
90% confidence level for the survey

Should Personal Health Information Be Included in HIE Only if Opt-In?



AHRQ: 2009
20 focus groups

- A majority want to “own” their health data, and to decide what goes into and who has access to their medical records (AHRQ p. 6).

- There was near universal agreement in all focus groups that if medical data are to be stored electronically, health care consumers should have some say in how those data are shared and used. (AHRQ p.29)

- A majority believe their medical data is “no one else’s business” and should not be shared without their permission. This belief was expressed not necessarily because they want to prevent some specific use of data but as a matter of principle. (AHRQ p. 18)

- Participants overwhelmingly want to be able to communicate directly with their providers with respect to how their PHI is handled, including with whom it may be shared and for what purposes. Most believe they should automatically be granted the right to correct misinformation (AHRQ p.33)

In fact, in the AHRQ Report they learned there was no support for the establishment of general rules that apply to all health care consumers. Participants thought that health care consumers should be able to exert control over their own health information **individually, rather than collectively**. (AHRQ p. 29)

AHRQ Publication No. 09-0081-EF "Final Report: Consumer Engagement in Developing Electronic Health Information Systems" Prepared by: Westat, (July 2009)

http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1248_888520_0_0_18/09-0081-EF.pdf

Institute of Medicine Survey: People Won’t Trust Research Without Privacy

by Dr. Alan F. Westin, October 2, 2007

- Only 1% agreed that researchers would be free to use personal medical and health information without consent
- Only 19% agreed that personal medical and health information could be used as long as the study “never revealed my personal identity” and it was supervised by an Institutional Review Board.

Why Opt-in?

- Consumers want choices and control
- Opt-out is deceptive/confusing
- Opt-out = opt-in to disclosure of all data to all users
- Public should not be forced into an "all or nothing choice" simply because some existing health IT doesn’t permit choices
- Facilitates technology innovation

The Business Case for Opt-in

- Opt-in = consumer trust and control
- Ability to disclose some or all information (segmentation, granular control)
- Dynamic
- Allows Data to be connected for health and research
- Facilitates AZ as national research center/jobs
- Builds on ABRC technology for research
- No lawsuits

ARRA—historic new privacy rights

Old rights:

- Providers may offer consent (Original HIPAA Privacy Rule), so patients can restrict disclosures
- Psychotherapy Notes require consent to disclose

New rights:

- Ban on sales of PHI (Protected Health Information)
- Segmentation
- Audit trails x 3 years
- Breach notice
- Encryption
- Patient can prevent disclosures of PHI for ‘payment and healthcare operations’ if pays out-of-pocket

Draft Amendment to SB 1258

Out of compliance with ARRA:

- No ability to segment information
- No ability to prevent disclosure for payment and healthcare operations
- Audit trails only required for 2 years, require purpose and details of disclosure

How to evaluate HIT legislation

- Does it reflect national requirements?
- Does it reflect what Arizonans want?
- Does it give Arizonans choice?
- Does it promote technology innovation?
- Is it constitutional? The AZ constitution includes a right of privacy

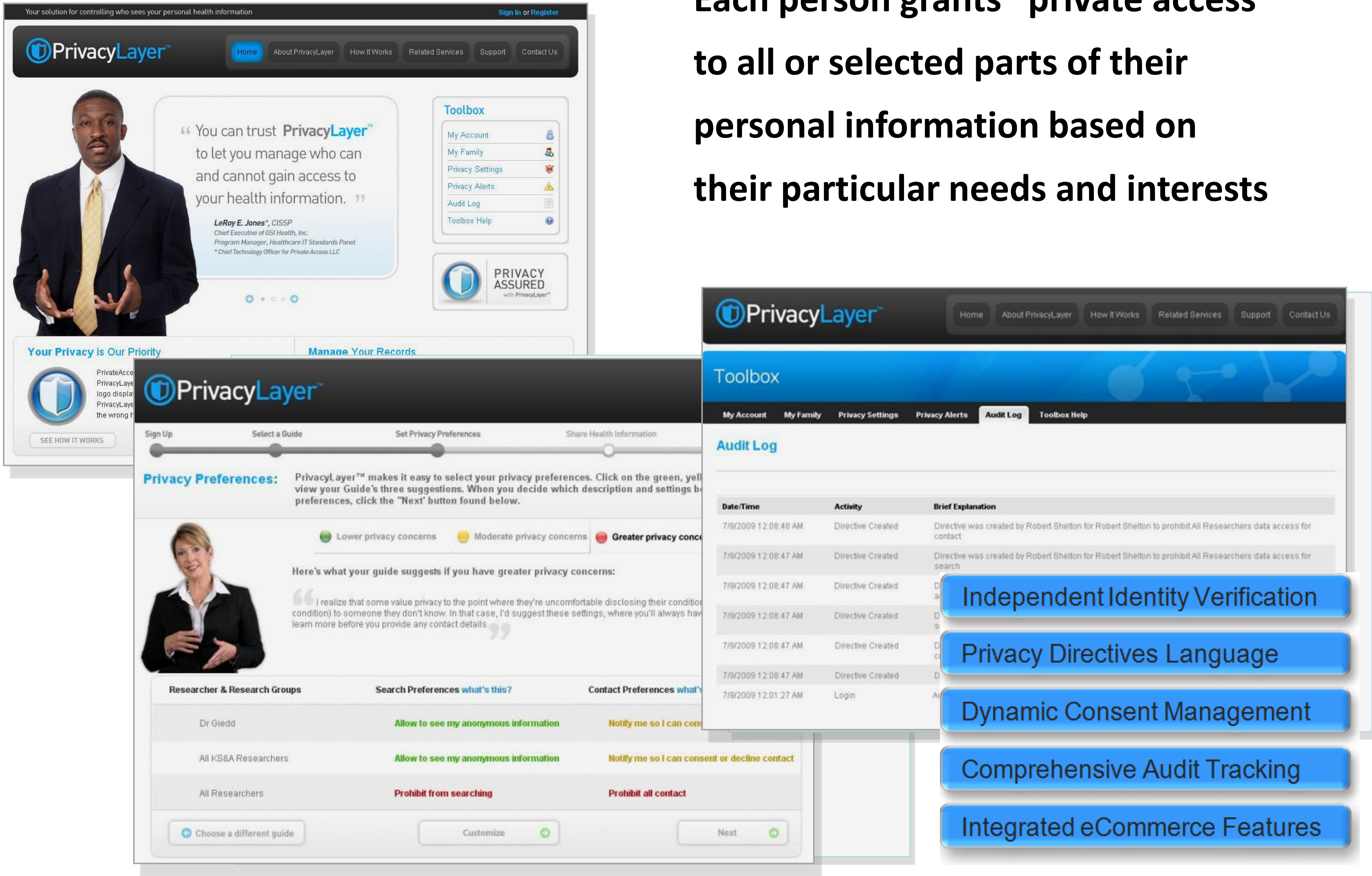
Opt-in Consent Solutions

Empowers the following choices:

- Opt-out of all use of PHI in HIO
- Opt-in to all uses of PHI in HIO
- Obtain copies of protected health information (PHI)
- Opt-in to all research use of PHI
- Opt-in to use or research with consent for each project

Consent Solutions So Far for Research Biobanks

Each person grants "private access" to all or selected parts of their personal information based on their particular needs and interests



Your solution for controlling who sees your personal health information

"You can trust PrivacyLayer™ to let you manage who can and cannot gain access to your health information."

LeRoy E. Jones*, CISSP
Chief Executive of GSI Health, Inc.
Program Manager, Healthcare IT Standards Panel
* Chief Technology Officer for Private Access LLC

Privacy Preferences: PrivacyLayer™ makes it easy to select your privacy preferences. Click on the green, yel view your Guide's three suggestions. When you decide which description and settings b preferences, click the "Next" button found below.

Here's what your guide suggests if you have greater privacy concerns:

I realize that some value privacy to the point where they're uncomfortable disclosing their conditio condition) to someone they don't know. In that case, I'd suggest these settings, where you'll always hav learn more before you provide any contact details.

Researcher & Research Groups	Search Preferences what's this?	Contact Preferences what's
Dr Giedd	Allow to see my anonymous information	Notify me so I can cons
All KS&A Researchers	Allow to see my anonymous information	Notify me so I can consent or decline contact
All Researchers	Prohibit from searching	Prohibit all contact

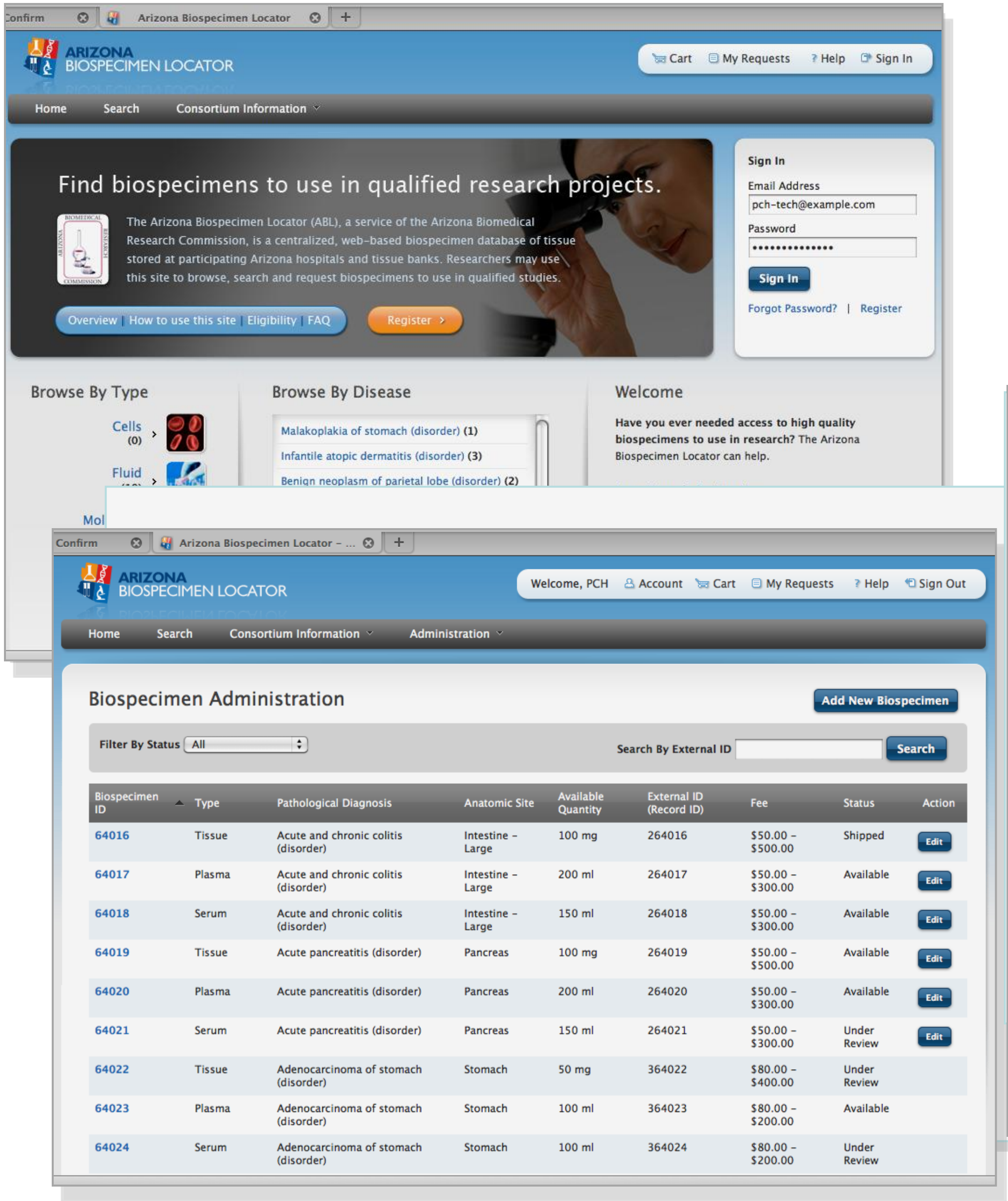
Audit Log

Date/Time	Activity	Brief Explanation
7/9/2009 12:08:48 AM	Directive Created	Directive was created by Robert Shelton for Robert Shelton to prohibit All Researchers data access for contact
7/9/2009 12:08:47 AM	Directive Created	Directive was created by Robert Shelton for Robert Shelton to prohibit All Researchers data access for search
7/9/2009 12:08:47 AM	Directive Created	D
7/9/2009 12:08:47 AM	Directive Created	D
7/9/2009 12:08:47 AM	Directive Created	D
7/9/2009 12:08:47 AM	Directive Created	D
7/9/2009 12:01:27 AM	Login	A

- Independent Identity Verification
- Privacy Directives Language
- Dynamic Consent Management
- Comprehensive Audit Tracking
- Integrated eCommerce Features

ABRC Biospecimen Locator Service

… consent can be integrated into cutting-edge applications such as services for locating biospecimens for use in qualified research projects



Find biospecimens to use in qualified research projects.

The Arizona Biospecimen Locator (ABL), a service of the Arizona Biomedical Research Commission, is a centralized, web-based biospecimen database of tissue stored at participating Arizona hospitals and tissue banks. Researchers may use this site to browse, search and request biospecimens to use in qualified studies.

Sign In

Email Address: pch-tech@example.com

Password: ••••••••••••••

Browse By Type

Browse By Disease

- Malakoplakia of stomach (disorder) (1)
- Infantile atopic dermatitis (disorder) (3)
- Benign neoplasm of parietal lobe (disorder) (2)

Welcome

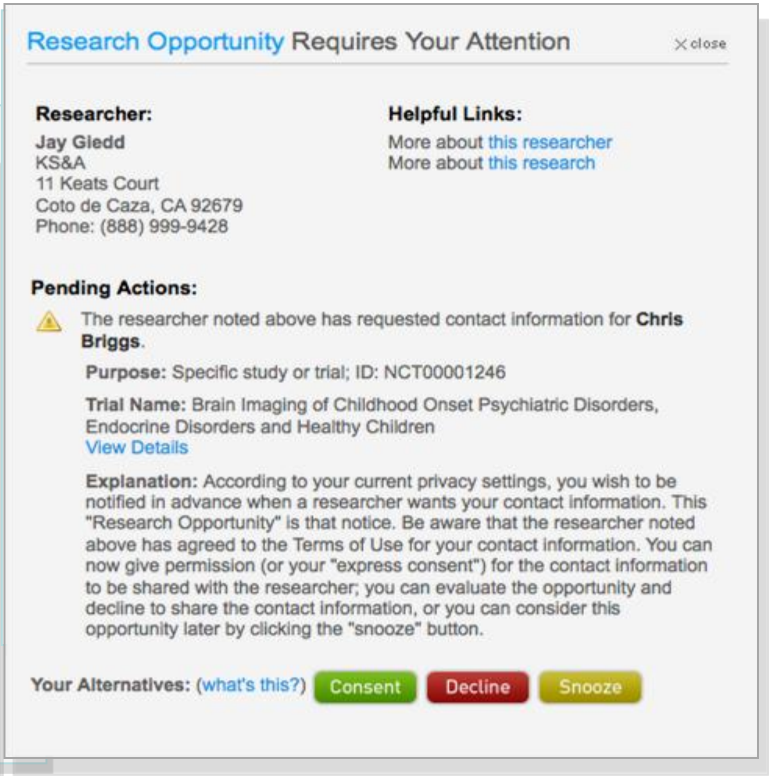
Have you ever needed access to high quality biospecimens to use in research? The Arizona Biospecimen Locator can help.

Biospecimen Administration

Filter By Status: All

Search By External ID

Biospecimen ID	Type	Pathological Diagnosis	Anatomic Site	Available Quantity	External ID (Record ID)	Fee	Status	Action
64016	Tissue	Acute and chronic colitis (disorder)	Intestine - Large	100 mg	264016	$50.00 - $500.00	Shipped	Edit
64017	Plasma	Acute and chronic colitis (disorder)	Intestine - Large	200 ml	264017	$50.00 - $300.00	Available	Edit
64018	Serum	Acute and chronic colitis (disorder)	Intestine - Large	150 ml	264018	$50.00 - $300.00	Available	Edit
64019	Tissue	Acute pancreatitis (disorder)	Pancreas	100 mg	264019	$50.00 - $500.00	Available	Edit
64020	Plasma	Acute pancreatitis (disorder)	Pancreas	200 ml	264020	$50.00 - $300.00	Available	Edit
64021	Serum	Acute pancreatitis (disorder)	Pancreas	150 ml	264021	$50.00 - $300.00	Under Review	Edit
64022	Tissue	Adenocarcinoma of stomach (disorder)	Stomach	50 mg	364022	$80.00 - $400.00	Under Review	
64023	Plasma	Adenocarcinoma of stomach (disorder)	Stomach	100 ml	364023	$80.00 - $200.00	Available	
64024	Serum	Adenocarcinoma of stomach (disorder)	Stomach	100 ml	364024	$80.00 - $200.00	Under Review	



Research Opportunity Requires Your Attention

Researcher:
Jay Gledd
KS&A
11 Keats Court
Coto de Caza, CA 92679
Phone: (888) 999-9428

Helpful Links:
More about this researcher
More about this research

Pending Actions:

The researcher noted above has requested contact information for **Chris Briggs**.

Purpose: Specific study or trial; ID: NCT00001246

Trial Name: Brain Imaging of Childhood Onset Psychiatric Disorders, Endocrine Disorders and Healthy Children
View Details

Explanation: According to your current privacy settings, you wish to be notified in advance when a researcher wants your contact information. This "Research Opportunity" is that notice. Be aware that the researcher noted above has agreed to the Terms of Use for your contact information. You can now give permission (or your "express consent") for the contact information to be shared with the researcher; you can evaluate the opportunity and decline to share the contact information, or you can consider this opportunity later by clicking the "snooze" button.

Your Alternatives: (what's this?)

Resources

- www.patientprivacyrights.org
- http://www.privateaccess.com/Pages/Home.aspx
- http://azabrc.gov/default.htm
- http://www.5amsolutions.com/

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www.patientprivacyrights.org

patientprivacyrights