informed CONsent for Clinical data Use for Research

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HIPAA and Protected Health Information

Security
  » Risk of unwanted disclosure
  » Liability

Privacy and Ethics
  » Risk of re-identification
  » (Un)informed consent
  » Data ownership


http://www.bioethics.gov covers genome sequencing, exome sequencing, genome-wide SNV analysis, and data from large scale genomic studies
Breaches Affecting 500 or More Individuals

As required by section 13402(e)(4) of the HITECH Act, the Secretary must post a list of breaches of unsecured protected health information affecting 500 or more individuals. These breaches are now posted in a new, more accessible format that allows users to search and sort the posted breaches. Additionally, this new format includes brief summaries of the breach cases that OCR has investigated and closed, as well as the names of private practice providers who have reported breaches of unsecured protected health information to the Secretary. The following breaches have been reported to the Secretary:

**Full DataSet [CSV format (18 KB)] [XML format (57 KB)]**

Select a column head to sort by that column. Select again to reverse the sort order. Select an individual record to display it in full below the table.

<table>
<thead>
<tr>
<th>Name of Covered Entity</th>
<th>State</th>
<th>Individuals Affected</th>
<th>Date of Breach</th>
<th>Type of Breach</th>
<th>Location of Breached Info</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st response Medical Transport Corp.</td>
<td>MD</td>
<td>552</td>
<td>06/15/2012-10/01/2012</td>
<td>Unauthorized Access/Disclosure</td>
<td>Desktop Computer</td>
</tr>
<tr>
<td>ABQ HealthPartners</td>
<td>NM</td>
<td>778</td>
<td>2012-12-20</td>
<td>Theft</td>
<td>Laptop</td>
</tr>
<tr>
<td>Accendo</td>
<td>AZ</td>
<td>175,350</td>
<td>2011-01-01</td>
<td>Unauthorized Access/Disclosure</td>
<td>Paper</td>
</tr>
<tr>
<td>Access Medical Group</td>
<td>PR</td>
<td>7,606</td>
<td>2012-01-11</td>
<td>Theft</td>
<td>Laptop</td>
</tr>
</tbody>
</table>
This bill would enact the Genetic Information Privacy Act, which would declare that an individual’s genetic information is protected by the right of privacy. The bill would prohibit any person from collecting, storing, analyzing, or disclosing genetic information without the written authorization of the individual to whom the information pertains, and would include related findings and declarations. It also would prescribe specific circumstances under which genetic information may be collected, stored, analyzed, or disclosed without the authorization.
(c) The commission urges federal and state governments to ensure a consistent floor of privacy protections covering whole genome sequencing data regardless of how they were obtained.

(d) Policies should protect individual genetic information by prohibiting the unauthorized use of surreptitious collection.

(e) It is the intent of the Legislature to enact legislation that would protect individuals from the unauthorized collection, storage, and disclosure of their genetic information.
(f) It is the intent of the Legislature to enact legislation that would ensure that genetic information is personal information that is not collected, stored, or disclosed without the **individual’s authorization**.

(h) It is the intent of the Legislature to enact legislation that would promote the use of genetic information for legitimate reasons, including, but not limited to, health care, research, advancement of medicine, and educational purposes, as the field of genomics advances.
Biometrics and Protected Health Information

Biometrics are Protected Health Information (PHI)

PHI requires HIPAA

• Biometrics require HIPAA
Genomes are Biometrics

- Biometrics are Protected Health Information (PHI)
- PHI requires HIPAA
- Biometrics require HIPAA
New DNA tests on a secret sample collected from a relative of suspect Albert deSalvo triggered the exhumation after authorities said there was a “familial match” with genetic material preserved in the killing of Sullivan...

Authorities made the match through DNA taken from a water bottle thrown away by DeSalvo’s nephew...

But a lawyer for the DeSalvos told CNN the family was “outraged, disgusted and offended” by the decision to secretly take a DNA sample of one of its members...
USE OF MEDICAL INFORMATION AND SPECIMENS:

I understand that my medical information, photographs, and/or video in any form may be used for other [INSTITUTION] purposes, such as quality improvement, patient safety and education. I also understand that my medical information and tissue, fluids, cells and other specimens (collectively, "Specimens") that [INSTITUTION] may collect during the course of my treatment and care may be used and shared with researchers.
I understand that under California law, I do not have any rights to any commercially useful products that may be developed from such research. I further understand that any use of my medical information or Specimens by [INSTITUTION] or other research institutions will be in accordance with state and federal law, including all laws and regulations governing patient confidentiality, in the manner outlined in the [INSTITUTION] Notice of Privacy Practices.
Enrollment in [research] studies can only occur after you have been informed about the study, had an opportunity to ask questions, and indicated your **willingness to participate by signing a consent form**. When approved through a special review process, **other studies may be performed using your medical information without requiring your consent**. These studies will not affect your treatment or welfare, and your medical information will continue to be protected.
Questions about clinical data sharing

• Which types of use require IRB approval?
  a. Quality improvement
  b. Research
  c. Public health

• Which types of data sets could be used for research without patient consent?
  a. De-identified
  b. Limited
  c. Identified

• What are the implications of improper disclosure?

• Can healthcare institutions honor individualized patient preferences?
Who is the data contributor?

MODEL 1. User downloads iDASH data

MODEL 2. User computes with iDASH hosted data in iDASH environment

MODEL 3. User performs iDASH computation in his own environment

Data Owner

Tool Creator

System Creator

HIPAA

User

DUA

QA

data 1

data 2

tool 1

tool 2

tool 3

VM 1

VM 2

VM 2

User A

User B

User C

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Patient Interface

Consent Management System
Do I wish to disclose data D to U?

Sharing Look-up
I can check that U looked at my data D

Yes

Healthcare Institutions

Trusted broker
• Data use agreements
• Study registry

User U requests Data D on individual I
Towards a “more informed” consent

- greater disclosure in the use of data and biospecimens
- simpler language in consent instruments
- a tiered consent mechanism

because

- patients may not know what they are sharing
- they may want to share more, or less, than what is currently shared

10/2/13

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DBP: patient-centered interaction

Patient accesses informed consent

Patient and investigator sign consent

Signed consent approved by IRB

File securely saved

Paper copy handed to patient

Courtesy of A Grando
Collection and Banking of Tissue, Blood and Urine for Use in Cancer Research
Principal Investigator: Richard Schwab M.D.
HRPP Project 09041

Assessment
Patient Self-Assessment

What is the purpose of this study?
Choose one of the following answers

- Gather samples for cancer research.
- Test different surgery procedures.
- Test different pathology procedures.
- Provide DNA results to cancer patients.

What will happen if you choose to participate?
Choose one of the following answers

- You will be asked to take an experimental drug to see if it helps treat your cancer.
- A sample of your blood will be stored for research use.
- You may get new information about your diagnosis.

Courtesy of A Rana
What is the value of multimedia?

160 Patients are recruited at Moores Cancer Center

Demographic Information is Collected

Consent form

Consent form

Self-Assessment and Survey

Patients will continue with biosample donation study

Educational Materials

Additional Info

Video

Images

Glossary

FAQs

No Educational Materials

Courtesy of A Grando
informed CONsent for Clinical data Use for Research

**iCONCUR**

- Patient / Consent Management System
- Sharing Look-up Registry
- Connecting Software
- Trusted Entity
  - Clinical Data Warehouse
  - Electronic Health Record
  - Healthcare Institution
- Query
- Results
- Concierge or Automated Services
- User U

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Research at the University of California

UC San Diego Health System is San Diego’s only academic health system. UCSD Health System has many healthcare components. Such as, medical centers, groups, clinics, and physician offices.

UC also conducts research. UC research looks for ways to improve health. You may not benefit directly from allowing your health information to be used in future research. But your data, together with data from many other patients, could help to shed light on certain diseases and treatments.

▶ How can your health information help research?

▶ What information could be shared?

▶ How will we protect your privacy and confidentiality?

▶ Who could have access to your health information?

▶ Will you be notified when UC shares your health records?

▶ Will you be able to change your mind about sharing your health records?

▶ What happens after the study finishes?

▶ If you have more questions:

Courtesy of A Grando
Tiered Permissions

- Demographics
  - Age, ethnicity, race, gender, marital status
- Laboratory tests
- Procedures
- Medications
- Diagnoses
  - Genetic information
  - Mental health & substance abuse
  - Sexual health & reproductive history
  - Domestic violence

Supported by the NIH Grant U54 HL108460 to the University of California, San Diego
• Who am I going to share my data with?
  » UCSD
  » All researchers from the University of California
  » Universities
  » VA
  » Non-profit institutions
  » Government
  » Commercial entities
  » Industry
## My current choices

<table>
<thead>
<tr>
<th>What clinical data I am sharing?</th>
<th>Who can access the clinical data I share?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Types of clinical data</td>
</tr>
<tr>
<td></td>
<td>□ UCSD and VA hospital</td>
</tr>
<tr>
<td>Demographics</td>
<td>✔</td>
</tr>
<tr>
<td>Diagnostic information</td>
<td>□</td>
</tr>
<tr>
<td>Non-sensitive information</td>
<td>✔</td>
</tr>
<tr>
<td>Sensitive information</td>
<td>□</td>
</tr>
<tr>
<td>Mental health information</td>
<td>□</td>
</tr>
<tr>
<td>Genetic information</td>
<td>□</td>
</tr>
<tr>
<td>Alcohol, substance and smoking</td>
<td>□</td>
</tr>
<tr>
<td>information</td>
<td>□</td>
</tr>
<tr>
<td>Reproductive and sexual health</td>
<td>□</td>
</tr>
<tr>
<td>information</td>
<td>□</td>
</tr>
<tr>
<td>Laboratory and test results</td>
<td>✔</td>
</tr>
<tr>
<td>Medical procedures</td>
<td>✔</td>
</tr>
<tr>
<td>Medications</td>
<td>✔</td>
</tr>
</tbody>
</table>
Goal was to understand:
• whether participants understood the idea of sharing medical information, and how to use the tool
• whether they want more options in the sharing taxonomies

28 questions, 40-50 minutes overall
• 3 questions in the evaluation designed to measure comprehension
• Overall score 90%

*Courtesy of E Bell*
Is there anything else that you would like to be able to keep private in your medical record?

- **No**: 22
- **Chronic Disease Information**: 4
- **Acute Disease Information**: 5
- **Sensitive non-diagnostic information**: 12
- **Other**: 2

*Courtesy of E Bell*
What to share / Who to share with

- 9 out of 40 (22%) do not want to share with commercially sponsored researchers
- 4 out of 40 (10%) want their medical information shared with only UCSD researchers, no others
- 10 out of 40 (25%) do not want to share at least 1 category of sensitive information
- Most common was genetic, followed by sexual & reproductive health

Courtesy of E Bell
If there was an option for you to control the sharing of biosamples, such as tissue, blood, and urine, would you want to be able to control this?

![Pie chart showing percentages]

35% Yes
45% No
20% I am indifferent

Courtesy of E Bell
If it were possible for you to know who is accessing your data, would you like to know it?

What would you like to know about the researchers who used your data?

- Yes
- No
- I am indifferent
- Other

What were the outcomes of their research
- Other 3

What papers they published using your data
- Other 32

What was the aim of their research
- Other 37

What kind of organization they belong to (e.g., a for-profit/non-profit organization, university, healthcare system)
- Other 36

Courtesy of E Bell
• Who did you share your data with?
• Which question did you help answer?
• Which data did you share?

eMERGE investigator Mary Smith, MD, PhD obtained 322 records for her study “Comparison of major bleeding events in patients with atrial fibrillation who are taking Pradaxa versus Coumadin”

Data You Shared:
Age: 53; Gender: F
Diagnoses: Atrial Fibrillation, Obesity
Medications: Dabigatran 100mg/day, Atenolol 100mg/day

Studies published about this work:

UCSD investigator George O’Connor, PhD obtained 230,938 records for his study “Correlation of age and Body Mass Index in postmenopausal women”

Data You Shared:
Age: 53; Gender: F; BMI: 30

There are currently no publications resulting from this work.
Do you feel more or less willing to share your medical information now that you had these choices?

70%

18%

12%

More  Other  Less

Courtesy of E Bell
Study with 200 medicine patients

Consent & Randomization

Consent Management System
\( I_1 \) can pick what I want to share with whom

Sharing Look-up
\( I_1 \) can check who or which entity looked at my data and what they could see

Outcome measures
- Proportion of revoked permissions
- Satisfaction
Acknowledgements

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Welcome to iDASH

Contemporary biomedical and behavioral research increasingly demands access to data-intensive computational resources. While the United States’ investments in information technology assets has created a rich national fabric to accelerate research, the number of bioscience researchers without these tools is increasing. By integrating secure, patient-anonymous data for analysis, anonymization, and sharing, iDASH is narrowing the gap by extending its infrastructure, tools, and services more broadly to the national biomedical, clinical, and informatics communities at universities, medical schools, and hospitals.

Created as a National Center for Biomedical Computing (NCBC) under the auspices of the NIH Roadmap for Bioinformatics and Computational Biology, iDASH is a Biomedical Cyberinfrastructure (BCI) that provides innovative services, algorithms, open-source software, and data storage as well as training.

Policy-based Secure Data Sharing

Welcome to iDASH

Science
Learn more about our driving biomedical and bioinformatics projects

Share/Access Data
Host and access data in a secure and privacy-preserving environment

Software/Tools
Advance your research and push your boundaries

CyberInfrastructure
Explore the fabric that binds all iDASH resources together

iDASH News

iDASH Second Annual All-Hands Symposium

http://idash.ucsd.edu

iDASH Privacy Workshop
September 29, 2012, UCSD, La Jolla, CA
Related work in genome research


How Altruistic is the Greater Good Community?

By Gregg Sparkman | April 27, 2012 | 0 Comments

The results are in from the Greater Good altruism quiz—and it turns out that gender, age, and income have significant connections to generosity.

Over the winter holidays, more than 1,600 Greater Good readers took our altruism quiz, which measures levels of generosity and giving.

After taking the quiz, participants learned how altruism might affect their happiness, and got tips on how to boost their charitable side.

So, Greater Good community, how altruistic are you?

Well, you averaged 84 out of 100 on the quiz, which was well into the high range of the altruism scale. At the end of the quiz, we asked a few questions about each person to see what qualities were linked to altruism. Here’s what we found.
Effect of Age and Gender on Altruism

http://greatergood.berkeley.edu/article/item/how_altruistic_is_the_greater_good_community