Patient Engagement Council
Webinar 3:
Privacy & Data Sharing

November 2014

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This toolkit was developed in full partnership with the PORTAL Patient Engagement Council (PEC) patient stakeholders. These materials may be used to help engage patients as research partners. The PEC is no longer a funded or active group. If you would like to reach out to one of the PEC members to engage them in a future project, please email Carmit McMullen, PhD, Senior Investigator, Kaiser Permanente Center for Health Research: Carmit.McMullen@kpchr.org.
Feedback on webinars so far

• What did we do well?
• How can we do better?

• Survey next time
Clarifying the Role of the PEC

PEC members will...

- Provide input about how to effectively engage patients and advocacy groups in research
- Share patient perspectives on privacy, confidentiality, informed consent, and how health research is conducted
- Identify outcomes and research questions that matter to patients
- Help to spread patient-centered research capacity
- Collaborate and facilitate communication between PORTAL and broader patient/community audiences
# Outline of Webinar

- Recap from October’s Webinar (Informed Consent)
- Today’s Webinar Goals
- The ABC’s of Privacy Regulations
- Overview Data Sharing
- Q & A
Recap of October Webinar

• In our last meeting, we learned:
  • How the informed consent process protects research participants
• In *this* webinar, we'll continue to learn about research participant protection, focusing on
  • Privacy Rights
  • Overview of Data Sharing
The **Institutional Review Board (IRB)** reviews research protocols and related materials. They protect human subjects from physical and psychological harm.

**Informed Consent** gives potential research participants enough information about a study to make an informed decision about whether or not to participate.

A **Human Subject** is a person whose health information is used by a researcher. Researchers can get this information by A) interacting with him/her; or (B) collecting individually identifiable health information, without interaction.
What we heard from you about informed consent:

• Written consent is often essential
• Communicate all elements of informed consent
• Participants need to know if they are being randomized
• Make sure that participants fully understand studies
• Make available both online and in-person options for informed consent
• Participants need readily available reference information about the study

Today we mostly focus on types of research that do not require informed consent
Continue learning about protecting research participants....

• The role of the IRB
• Informed Consent
• Next step: How is your privacy protected?
The goals of this webinar are for you to

Understand privacy of health data in research

Understand how privacy protection relates to PORTAL activities

Build a foundation to provide informed feedback on our next Webinar: PORTAL Governance
Health Insurance Portability and Accountability Act (HIPAA)

**What:** A law issued in 1996 by the U.S. Department of Health and Human Services (DHHS)

**Why:** To provide national standards for protecting the privacy of health information

**How:** Gives patients control over the use of their health information

- Defines how health information may be used and shared across **covered entities** (each PORTAL health plan and KP region is a covered entity)
- Limits release of information to the minimum necessary
- Holds violators accountable with civil or criminal penalties
HIPAA was enacted in response to problems with health care coverage, privacy, security, and fraud in the United States.

Healthcare coverage: Enabled individuals to keep their health insurance between jobs.


Not research focused, but has had big impact on research.
HIPAA applies to data created by healthcare providers, health plans and researchers

- HIPAA applies to data that is individually identifiable

- PORTAL researchers must abide by HIPAA when using data
Your information can be used or disclosed with your signed authorization in research studies. (Usually at the time of informed consent)

Your information can be used or disclosed without your authorization, if:

- IRB or Privacy Board give researchers a waiver from getting authorization (according to HIPAA regulations)
- The data will be used only to see if a study is feasible (grant writing, preparation for research)
- The health information is about someone who is deceased
The Minimum Necessary Standard

Health plans must limit unnecessary or inappropriate access to and sharing (disclosure) of personal health information. They do so by:

1. Taking reasonable steps to limit access and disclosure to the minimum necessary to accomplish the intended purpose.
2. Evaluating their practices and enhancing safeguards.
3. Developing and implementing policies and procedures appropriate for each organization, reflecting the organization’s business practices and workforce.

In PORTAL, each of our regions and health plans may have slightly different ways of interpreting the minimum necessary standard.
Protected Health Information (PHI)

Individual-level information (verbal, written, electronic) created or received by a healthcare provider, health plan, or researcher that contains any of the following:

- Physical or mental health or condition
- Health care services received, and payment for health care
- Communications between a patient or participant and their health care provider or researcher about their care.

AND combined with at least one of the following 18 identifiers....
### 18 Identifiers

| 1. Names, including derivatives (e.g., initials) | 7. Email addresses | 13. Biometric identifiers, including finger and voice prints |
| 2. Geographic locations smaller than a State (including street address, city, county, precinct, zip code) | 8. Medical record numbers | 14. Vehicle identifiers and serial numbers, including license plate numbers |
| 4. Fax numbers | 10. Account numbers | 16. Internet Protocol (IP) addresses |
| 5. Social Security numbers | 11. Certificate/license numbers | 17. Full-face photographic images of participants and any comparable images |
| 6. Dates more specific than year (including DOB, service dates, etc.) | 12. Medical device identifiers and serial numbers | 18. Any other unique identifying number, characteristic or code that could be used alone or in combination with other information to identify an individual |
Which pill bottle label contains PHI?

A
B

Does this email message contain PHI?

To: Customer Service-KPIT
From: Jane Smith
Add Bcc
Subject: Joe Patient
Attach a file
Insert: Invitation

Please remove this deceased member's phone number from the automatic reminder telephone call list. Joe Patient, MRN 1A2B3C4D. Death date 4/02/12.

Yes
No

If used to pay for a member’s cost share, is credit card information considered PHI?

Yes
No

Does this wristband contain PHI?

Yes
No
How is your privacy protected?

[Image: Medical Release Form]
[Image: Lock and key]
[Image: Password dialog box]
[Image: Secure email interface]
Types of Health Information

- **Protected Health Information**: Health information (data) combined with at least one of the 18 identifiers.

- **Limited Data Sets**: Health Information (data) paired with ONLY the following identifiers:
  - Dates
  - General geographic information
  - Ages when greater than 89 years

- **De-identified Data**: Data that has NONE of the 18 identifiers

Less privacy risk, less regulation about disclosure
How will PORTAL use and share data?

• The Common Data Model (or CDM) is a way of organizing data into a standard structure. Each PCORnet network is currently matching their data to the same consistent format.

• Doing this now creates a platform for more rapid responses to research-related questions in the future.

• More efficient than having to transform and prepare data each time we want to ask a new research question.

• For example:
  “Birth_DT”
  “Date_of_Birth”
  “DOB”  \(\rightarrow\) “BIRTH_DATE”
Introduction to Data Sharing

Databases remain at each site/covered entity

Data can be shared between PORTAL sites for research

All the PORTAL sites have signed legal documents with each other, setting out rules for sharing data (including PHI)
Query Flow Diagram

1. PCORnet Coordinating Center sends PMN query to PORTAL Sites. Each site has the option to opt out of any particular query.

2. Site runs query, results created. Results can be either de-identified data or individual level. Sites share data via PMN with the PORTAL DCC.

3. The PORTAL DCC verifies that data sets from each site adhere to PORTAL governance standards, before releasing data results to the PCORnet Coordinating Center.

4. PCORnet Coordinating Center receives site data from all participating sites, and aggregates data sets prior to reporting results in accordance with the PCORnet governance policies.

* What type of data is the Site Data?
  - de-identified data sets
  - individually identifiable data sets

HPHCI - Harvard Pilgrim Health Care Institute
PMN - PopMedNet
DCC - Data Coordinating Center

Site data

Multi-site aggregated study results to be disseminated
## How PCORnet will use data

<table>
<thead>
<tr>
<th>Use</th>
<th>Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counting cohort members across networks (NO PHI)</td>
<td>Network sends coordinating center a count of how many people have a given diagnosis or procedure</td>
<td>Count of individuals with diagnosis of obesity % individuals with that diagnosis who are under 20 years old</td>
</tr>
<tr>
<td>Cohort summary statistics across networks (NO PHI)</td>
<td>Analysis of patient-level data within each network, sent to coordinating center</td>
<td>How many patients taking medication X have a heart attack during one year?</td>
</tr>
<tr>
<td>Cohort lists for re-identification and recruitment for studies (POTENTIAL PHI)</td>
<td>Coordinating center receives subject IDs that each network can later link back to individual members</td>
<td>Sending surveys to patients who have had bariatric surgery</td>
</tr>
<tr>
<td>Expanded data sources (PHI)</td>
<td>Combining health plan data with external data</td>
<td>Fitbit, e-diaries, clinical trial data, etc</td>
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</tbody>
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*Adapted from PCORnet’s Data Standards, Security and Network Infrastructure*

Why this All Matters

• To conduct powerful research PORTAL sites must be able to share health data amongst themselves (Kaiser Permanente regions, Denver Health, Health Partners, and Group Health) for research purposes

• This data sharing will expand opportunities to translate research findings into improvements in healthcare
Where are we going with all of this?

PEC Input is part of the puzzle needed to build PORTAL’s research protocols.
Next Webinar, we will ask for your input in developing components of PORTAL governance
December Webinar

Topic of Discussion:

Governance Document & Data Sharing
Glossary of Privacy Terms

• **Health Insurance Portability and Accountability Act (HIPAA)**
  Federal law that provides national standards for protecting the privacy of health information

• **Covered Entity**
  A person, organization, or business which is federally regulated to protect the privacy and security of individuals’ health information
  
  *In the PORTAL network, each health plan and each KP region is a covered entity*

• **Protected Health Information (PHI)**
  Individually identifiable health information that is transmitted or maintained in any form (electronic, oral, or paper) by a covered entity

• **Disclosure**
  To share or provide access to PHI to a person or group outside of a covered entity.

• **Identifiers**
  Names, social security numbers, medical record numbers, or pathology record numbers, or any other “code” that permits specimens or data to be linked to individually identifiable living individuals.