The Office of the National Coordinator for Health Information Technology

Patient Centered Outcomes Research (PCOR) Privacy and Security Research Scenario Initiative and Legal Analysis and Ethics Framework Development

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Presentation Agenda

- Project Overview: PCOR Privacy and Security Research Scenario Initiative and Legal Analysis and Ethics Framework Development Project
- Final Product: Legal and Ethical Architecture for PCOR Data

Project Overview

Supported the development of a **legal and ethical architecture to enable robust PCOR,** while providing sufficient assurance to stakeholders that data used for PCOR will be protected and secured as required by applicable statutes and regulations

Project Overview (2)

Phase 1:

- Convene discussions with stakeholders in PCOR community.
- Develop research scenarios and data use cases.

(Led by NORC)

Phase 2:

- Assess the legal, regulatory, and policy environment governing the use of health information for PCOR.
- Develop a legal and ethical framework and architecture for access to data for PCOR while protecting patient privacy.

(Led by the George Washington University)

Legal and Ethical Architecture for PCOR Data

- Collection of tools and resources designed to:
  - Provide a common structure and model of analysis of legal requirements and ethical considerations and responsibilities for research, particularly PCOR;
  - Support PCOR and CER through illustrative pathways for collecting and sharing data for research in compliance with relevant federal laws and regulations and in consideration of state law; and
  - Support a culture of trust between and among stakeholders through the application of meaningful and appropriate privacy and security parameters.

Designed for Broad Audience

- Primary Audience
  - Researchers engaged in PCOR and CER
  - IRBs
  - Contracting Officers
  - Research and Development Officers
  - Compliance and Privacy Officers
  - Internal/External Legal Counsel
- Wider Audience
  - Federal and state legislative and regulatory bodies
  - Foundations and other organizations that fund research
  - Policy analysts
  - Patient advocates
  - Lawmakers
  - Academics
  - Students

Architecture Overview

- Chapter 1: Overview
- Chapter 2: Legal and Ethical Significance of Data for PCOR
- Chapter 3: Linking Legal and Ethical Requirements to PCOR Data
- Chapter 4: Framework for Navigating Legal and Ethical Requirements for PCOR
- Chapter 5: Mapping Research Data Flows to Legal Requirements
- Appendices
  - A: Summary of Statutes and Regulations Relevant to PCOR
  - B: Assessing Potential Barriers and Ambiguity in the Legal Landscape
  - C: Selected Federal Initiatives
  - D: Selected Federal Resources
  - E: Glossary

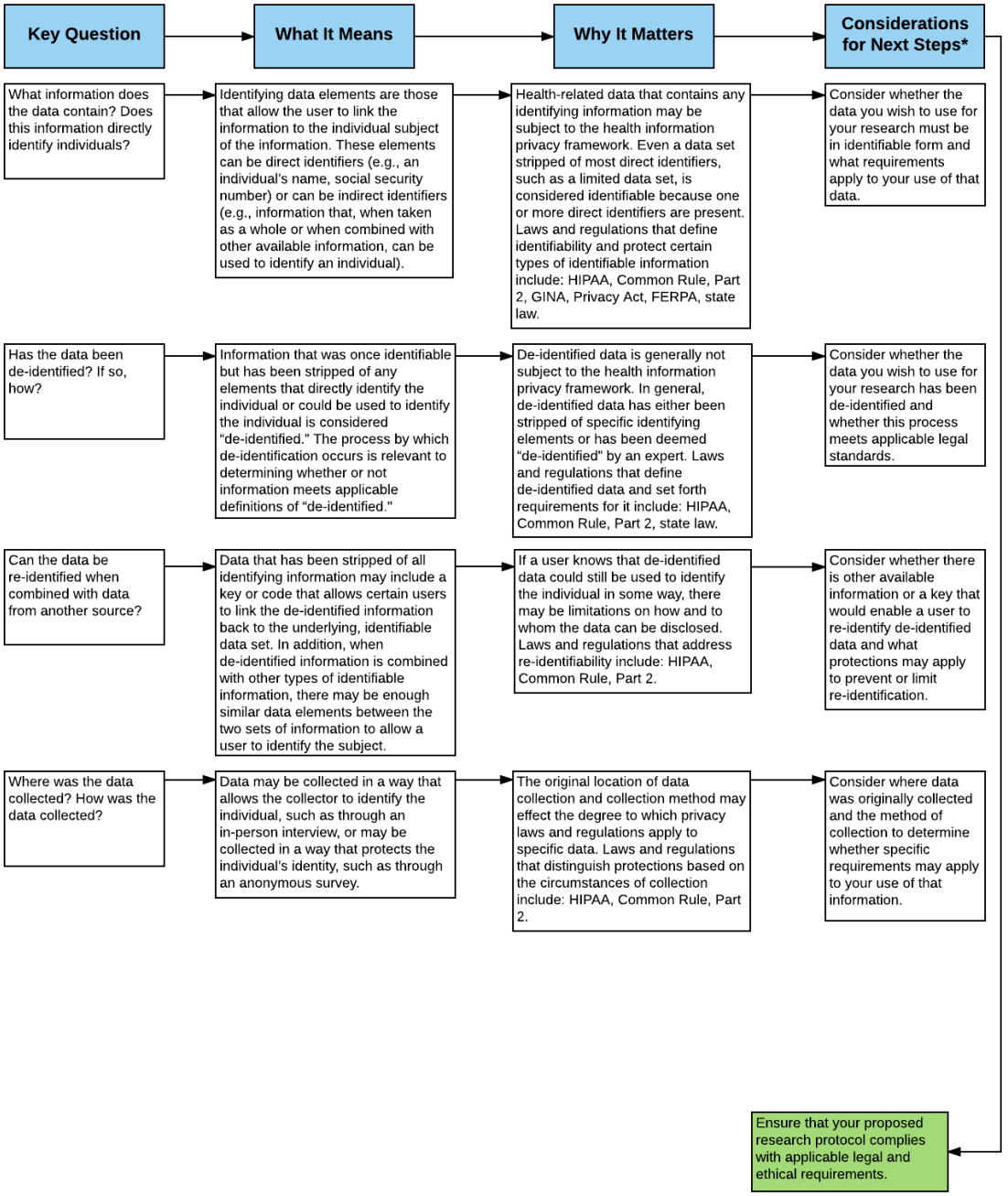
Chapter 4: Framework for Navigating Legal and Ethical Requirements for PCOR

- **The Framework is a visual decision tool that highlights key characteristics and considerations associated with the spectrum of data used for PCOR and the nature of the relationships between researchers and other stakeholders.**
- **Groupings and color coded key characteristics direct stakeholders to factors determining:**
  - » Whether a statute or regulation applies to the data;
  - » How a researcher should navigate statutes/regulations that apply to the data; and
  - » Whether there are case-specific determinations relating to data collection and use.

Why would a stakeholder use Chapter 4?

To identify relevance and importance of legal requirements and ethical principles detailed in Chapter 3 that may apply to the use of/access to data for PCOR depending on specific data characteristics described in Chapter 2.

Example of the Framework: Identifiability



*GENERAL NOTE: In all cases, researchers should consult legal counsel (in-house or external), individual IRB practices, and organizational policies and procedures. Relevant parties may include privacy boards or officers, compliance committees or officers, research managers or contracting personnel, and other legally responsible parties.

Chapter 5: Mapping Research Data Flows to Legal Requirements

- **Data Flows adapted from Phase 1 research scenarios**
  - General Data Flow
  - Combining Data for PCOR
  - Consent Management
  - Release and Use of Specially Protected Health Data
  - Identification and Re-Identification of PCOR Data
  - Research Using Patient-Generated Health Data
- **All Data Flow Maps outline key steps likely to be encountered in the course of PCOR research.**
  - Includes associated legal trigger/decision points
- **The General Data Flow provides a foundational example of the mapping process.**

Why would a stakeholder use Chapter 5?

To understand how relevant statutes and regulations apply to specific research scenarios (step-by-step illustrations).

Data Flow Example

Step	Scenario Data Flow	HIPAA	The Common Rule	State Law
4	Individual seeks treatment at the FQHC for asthma. Individual's mother consents to his treatment. Individual's BMI is recorded in the obese range. Individual's information is maintained within the FQHC's EHR system along with other patient medical records.	The HIPAA Privacy and Security Rules apply to CEs, which are healthcare providers, health plans, and healthcare clearing-houses. *See HIPAA Note 1.* Individually identifiable health information provided by an individual to a CE becomes HIPAA-covered PHI once received by the CE and stored in their records. *See HIPAA Note 2.* The HIPAA Security Rule generally requires that PHI be stored and transmitted with appropriate protections in accordance with the Security Rule's provisions. *See HIPAA Note 3.*	--	State law defines the age of majority and also defines the ages at which minors may consent to medical treatment or research (which may vary based on type of treatment or research). *See State Law Note 3.* For a minor or legally incompetent patient or research participant, state law determines who is empowered to provide consent as the individual's parent or legal guardian. *See State Law Note 3.*
5	At time of treatment, FQHC recruits Individual to participate in research study in which Individual's health data collected in the course of treatment will be reported to Research Institution at quarterly intervals. Individual's mother consents to Individual's participation in the research study and for Individual's information to be given to Research Institution.	Generally, a CE must obtain authorization from the subject of the information to disclose PHI to a researcher for research, with limited exceptions. *See HIPAA Note 9.* HIPAA Authorization to disclose PHI may be combined with consent to participate in research (compound authorization). *See HIPAA Note 11.*	Informed consent is required unless the IRB waives it in full or in part. *See Common Rule Note 6.* For minors participating in research, the consent of a single parent may be sufficient for certain studies. *See Common Rule Note 7.*	For a minor or legally incompetent patient or research participant, state law determines who is empowered to provide consent as the individual's parent or legal guardian. *See State Law Note 3.*
6	Per the approved research protocol, FQHC also obtains Individual's assent to participate in the research.	--	Assent to participate in research is required for children capable of providing consent, as determined by an IRB. *See Common Rule Note 8.*	--

Acronyms for Data Flow

CE = Covered Entity
EHR = Electronic Health Record
FQHC = Federally Qualified Health Center
IRB = Institutional Review Board
PHI = Protected Health Information

Potential Uses of the Framework

- Journal publication
- Adoption of legal and ethical framework and architecture through PCORTF projects
- Inclusion of legal and ethical framework and architecture in research studies involving PCOR
- Use of legal and ethical framework and architecture to be considered a best practice for PCOR and other research studies

The Office of the National Coordinator for Health Information Technology

Thank You

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