RESEARCH DATA GOVERNANCE: BEST PRACTICES AND CASE STUDY

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SPEAKERS

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Vice President, Chief Privacy Officer at CVS Health

Tracey Scraba is Vice President and Chief Privacy Officer at CVS Health. She has enterprise-wide responsibility for CVS Health's privacy program, including daily operations of the privacy office, development and implementation of privacy and policies and procedures, monitoring privacy compliance, information governance, incident investigation, breach response, and providing privacy and security legal support.

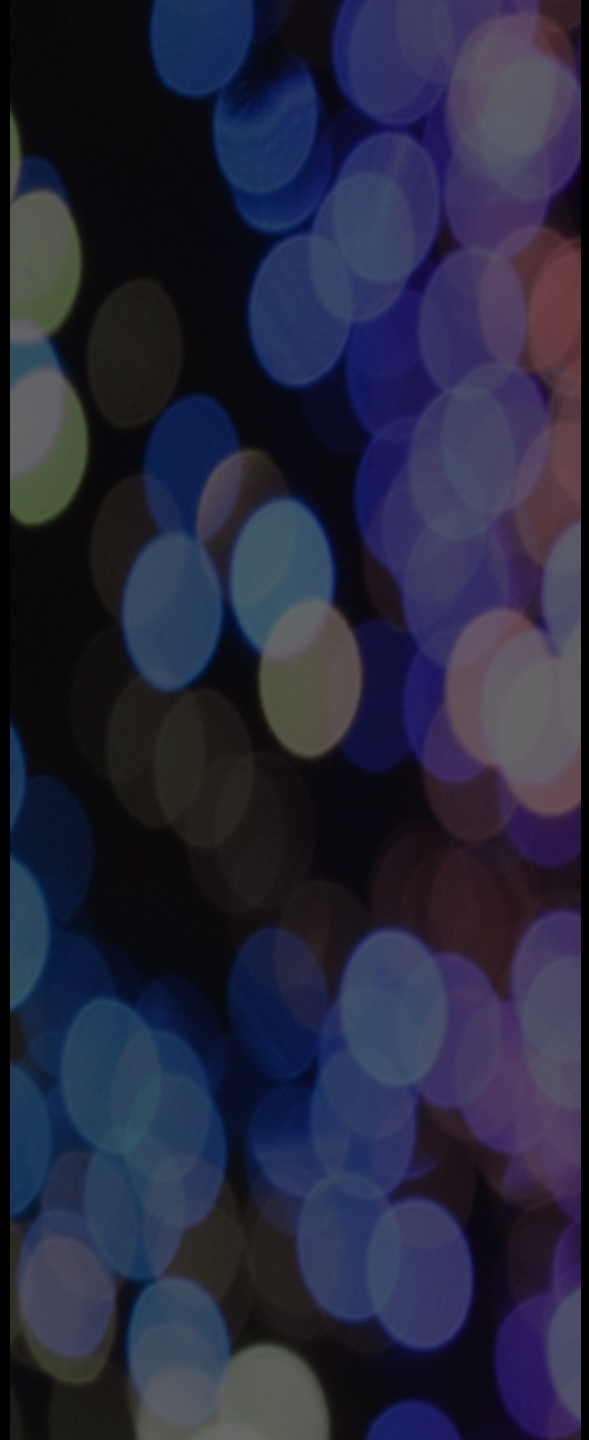
William J. Roberts, Esq.

Partner, Co-Chair Data Privacy

William J. Roberts is the Co-Chair of Shipman & Goodwin LLP's Data Privacy and Protection Practice. He advises a wide range of companies and organizations from around the globe on data privacy and security matters, including with respect to regulatory compliance, data breaches, and government investigations. He is a Certified Information Privacy Professional (CIPP/US) through the International Association of Privacy Professionals (IAPP).

AGENDA

- Purpose of a Research Data Governance Program
- Structure of a Research Data Governance Program
- Case Studies



OVERVIEW AND OBJECTIVES

- A Research Data Governance Program is an important tool which helps health care sector organizations ensure that the entity's data is used and disclosed for research purposes in a compliant and ethical manner
- Compliance Objectives:
  - HIPAA
  - Common Rule
  - Compliant authorizations, Data Use Agreements

OVERVIEW AND OBJECTIVES

oEthical Objectives:

- Consistency of the proposed research with the entity's mission and values
- Serve as a "check" on individual researchers
- Ensure appropriateness of 3rd party collaborations

oProcess Objectives:

- Consistent pathway for an organization to receive and evaluate research proposals and requests for data
- Uniform review mechanism to ensure appropriate stakeholders are involved and important questions asked
- Ensure documentation of evaluation process and ultimate decision

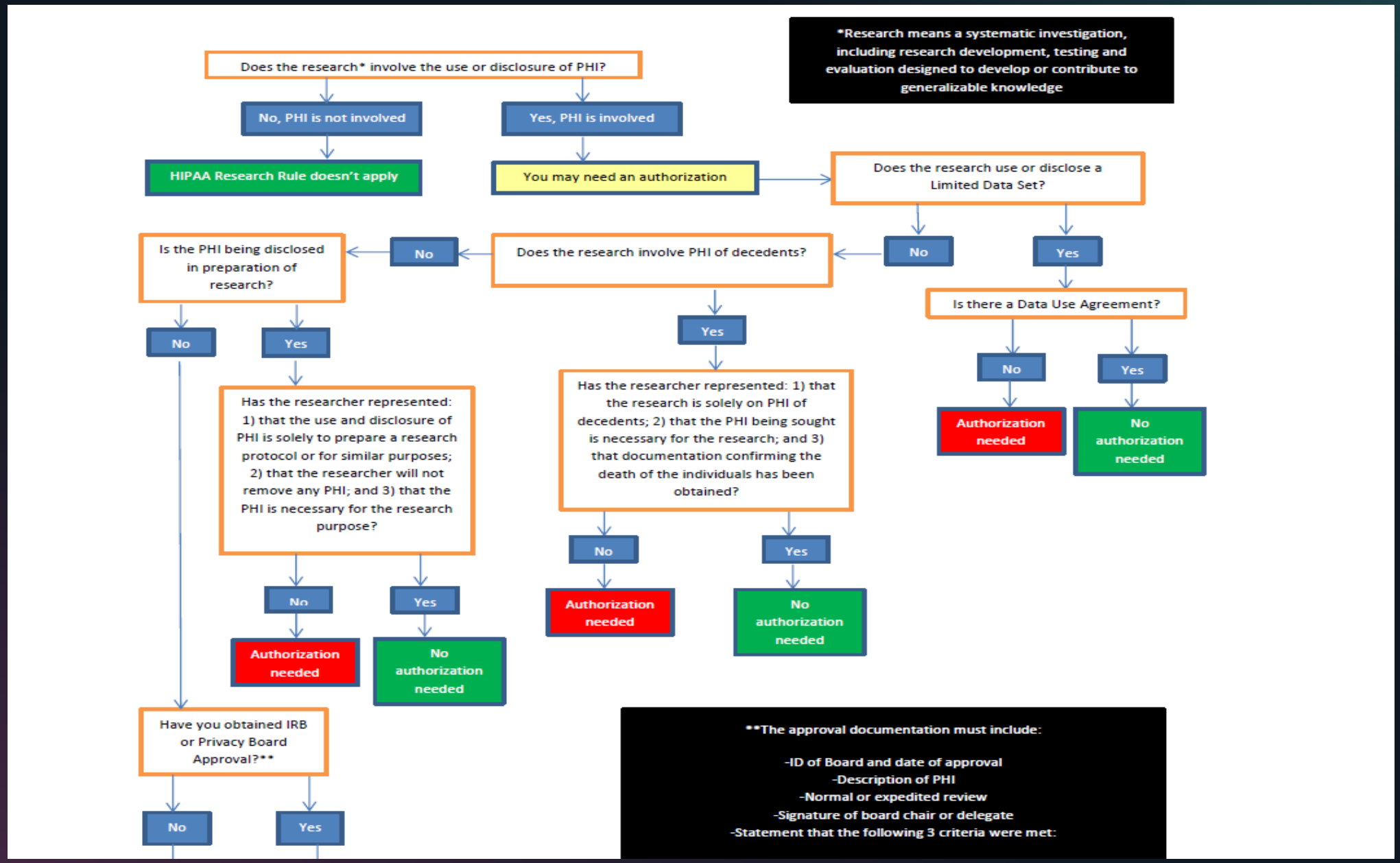
OVERVIEW AND OBJECTIVES

- Organizational Objectives:
  - Utilize data assets in a manner to further the organization's purpose, such as improving health care, reducing disparities, reducing costs, and supporting quality care
  - Consider uses and disclosures of data for research purposes efficiently – don't overburden
  - For more mature programs, consider the Research Data Governance Board's role in improving data collection (i.e. what data does the organization collect and maintain, and why?) and data quality

KEYSTONE ELEMENTS FOR USE OR DISCLOSURE FOR RESEARCH PURPOSES

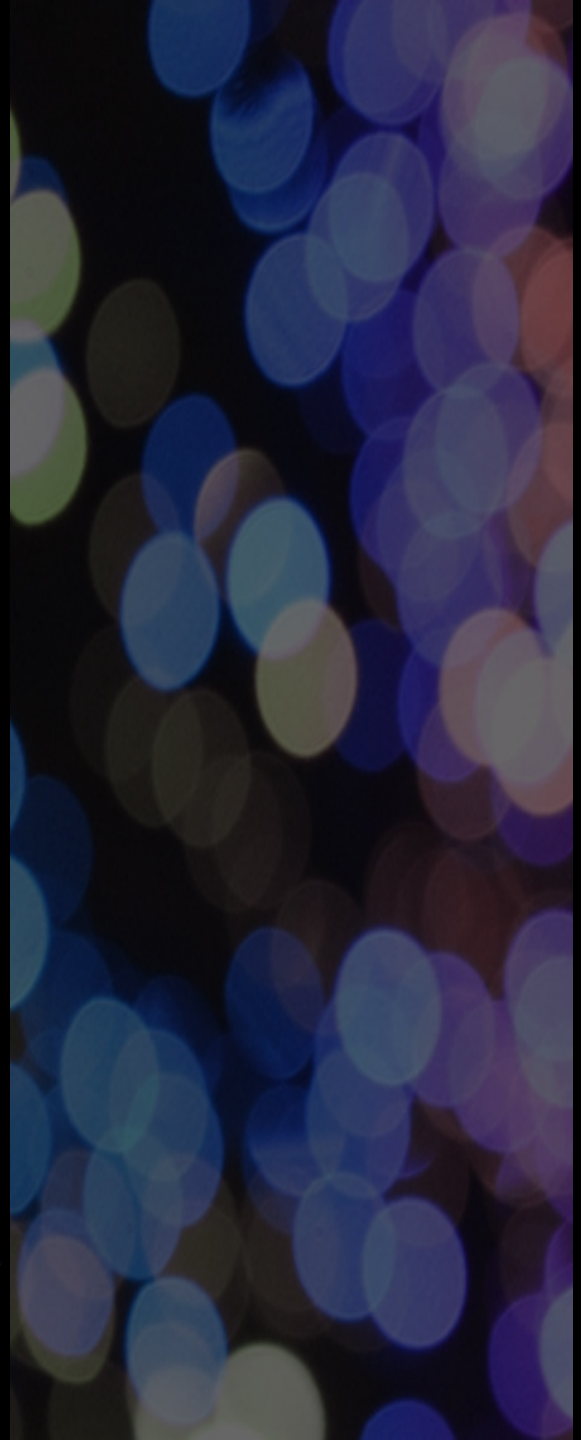
- Is the use or disclosure for "research" purposes?
- Does the use or disclosure require PHI?
- Is the request for only a Limited Data Set?
- Is the request for PHI of decedents?
- Is the PHI being disclosed in preparation for research?
- Has an IRB or Privacy Board waived the authorization requirement?
- Is there documentation of the review and approval process?

SAMPLE DECISION TREE



RESEARCH DATA GOVERNANCE - STRUCTURE

- Establishment of a Data Governance Board
- Governing Charter
- Approved Process and Template Documents
- Defined Role for In-House Counsel

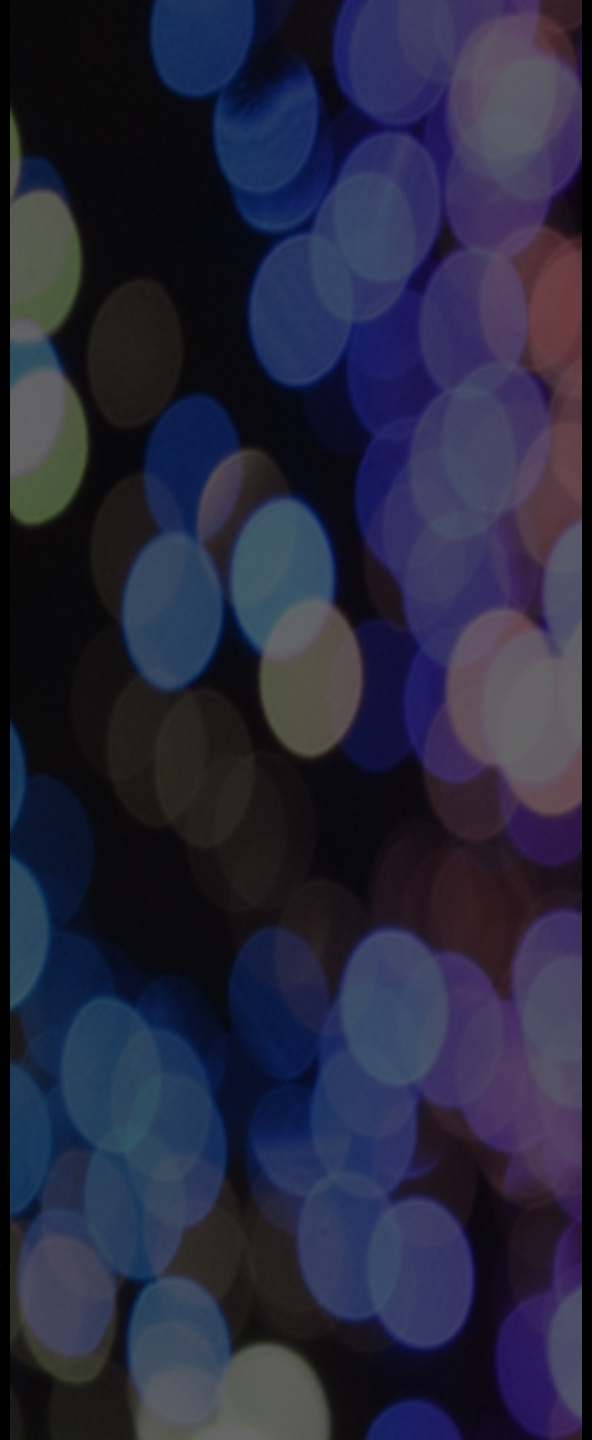


IMPORTANCE OF GOVERNANCE BOARD

- Ensure cross-department accountability and ownership
- "One-stop shop" to confirm compliance with regulations and other obligations
- Encourage data safeguards for non-typical TPO uses
- Awareness of ongoing partnerships with institutions

GOVERNANCE BOARD BEST PRACTICES

- Board participants need to be well-defined and represent a cross-function and cross-section of the business
- Privacy pre-screen
- Prior to being reviewed, all research projects must have:
  - An executive sponsor;
  - Defined data needs/requirements; and
  - Operational support (i.e., have a plan for how they are going to get the information they need)
- A "fast track" option



GOVERNANCE BOARD COMPOSITION

- Composition of a typical research data governance board:
  - "Impartial" project manager
  - Business strategy officer
  - Legal and compliance (including privacy)
  - Information security
  - "Frequent fliers"

EVALUATION OF PROPOSED RESEARCH ACTIVITIES

- Business strategy: institutional, plan sponsor and provider partnerships, consistent with enterprise priorities
- Risks: reputational, regulatory/compliance, information security
- Ethics and Transparency: “Front Page Test”
- Operations: relationship manager and executive support for ongoing research needs

APPROVED PROCESS AND TEMPLATE DOCUMENTS

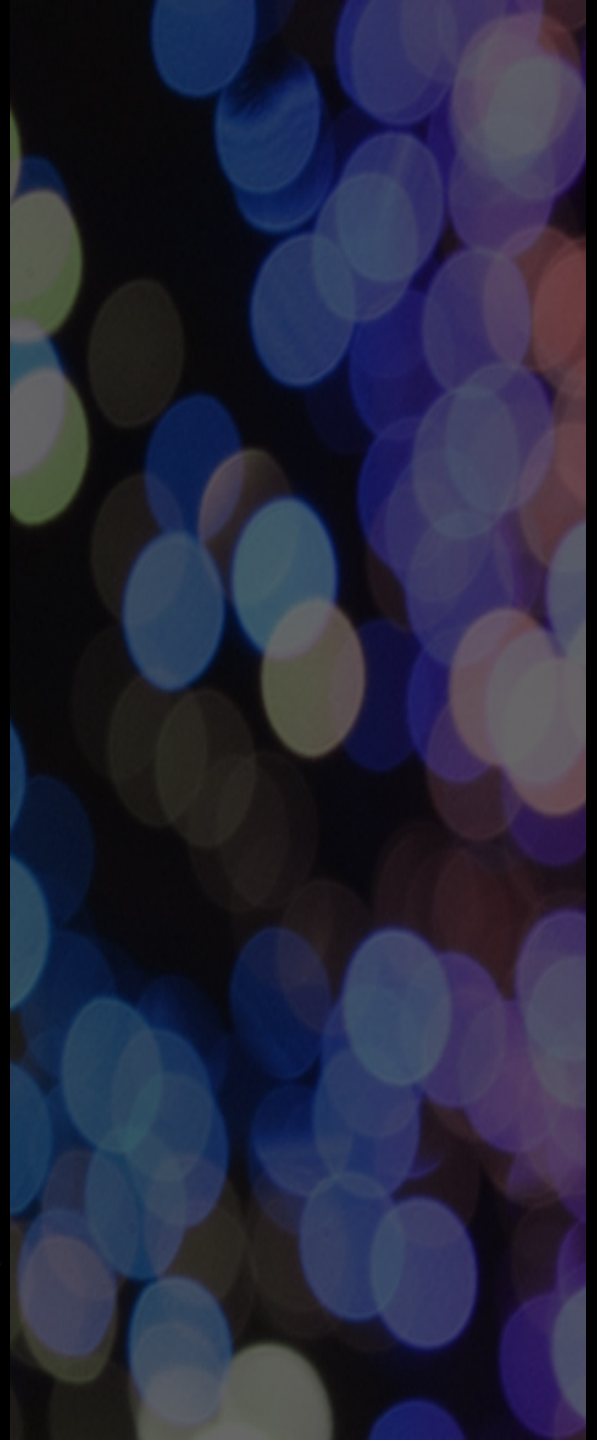
- Data governance board charter
- Pathway for research proposals
  - Intake
  - Initial document and information requests
- Standard review process
  - Research or health care ops/quality improvement?
  - Consistent evaluation points
- Template documents
  - Process for evaluating and approving revisions

ROLE OF IN-HOUSE COUNSEL

- In-house counsel helps to:
  - Define research vs. health care operations
  - Define the legal requirements for research
  - Provide the agreements to enable research, after board approval (develop templates, negotiate terms with third parties engaged in research)

CASE STUDY #1

- The Story: A sociology professor is interested in studying health outcome disparities. She submits a request for patient records to City Hospital.
- Analysis:
  - Are authorizations contemplated?
  - Has the study been reviewed by an IRB? If so, were waivers issued?
  - How will the results be used? What may they show about the care the hospital provides?
  - What do we know about the professor or the institution? Are we comfortable with their compliance history and institutional safeguards?



CASE STUDY #2

- The Story: An InsurTech start-up company approaches a regional health insurer for access to PHI. The InsurTech has a data scientist on its Board and the data scientist wants to test its AI product on member data to identify where care interventions should have been made.
- Analysis:
  - Is this research?
  - Does HIPAA permit the disclosure of PHI for this purpose?
  - May de-identified data be sufficient?
  - What is the business case/risk of sharing the data? Does the disclosure align with business strategy?

QUESTIONS AND DISCUSSION