
# All In Webinar: Navigating Consent Resource List

**Health Info Law**

- HealthInfoLaw.org offers keys to understanding the laws that govern health information and the implications they can have across health care and beyond. A project of the George Washington University's Hirsh Health Law and Policy Program, Health Information and the Law, developed with support from the Robert Wood Johnson Foundation, is designed to serve as a practical online resource to federal and state laws governing access, use, release, and publication of health information.

**Health Information Data Sharing**

- The National Network for Public Health Law offers a number of resources, including a legal assistance library, issue briefs and customized technical assistance. Experienced Network attorneys are ready and able to provide technical assistance and guidance on any legal or ethical issue that arises from the collection, use, storage and/or disclosure of data by public health agencies. For legal technical assistance and support on accreditation of public health agencies, please contact your region.

**Federal Data-Sharing Laws and Policies**

- **The Common Rule**
  The Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and codified in separate regulations by 15 Federal departments and agencies. For all participating departments and agencies the Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance.

- **Fact Sheet: Permitted Uses and Disclosures: Exchange for Health Care Operations**
  ***Office of the National Coordinator for Health IT, HHS Office of Civil Rights***
  This resource discusses how healthcare organizations can share patient Protected Health Information (PHI) for operational and administrative purposes under HIPAA.

- **Fact Sheet: Permitted Uses and Disclosures: Exchange for Treatment**
  ***Office of the National Coordinator for Health IT, HHS Office of Civil Rights***
  Fact sheet discusses how healthcare organizations can share the Protected Health Information (PHI) of patients for care coordination and treatment purposes per HIPAA regulations.

- **Legal Issues in the Use of Electronic Data Systems for Social Science Research**
  ***John Petrila, J.D., LL.M. for Actionable Intelligence for Social Policy***
  This paper reviews issues associated with data-sharing for social science research. The authors discuss federal and state laws that affect the privacy levels of social science datasets and describe the IRB (Institutional Review Board) process. Lastly, it summarizes current laws on electronic health data use and security, with respect to HIPAA, and the consequences of violating confidentiality laws.

**Managing Privacy and Consent through Data Governance Principles**

- **Privacy, Fairness, and Respect for Individuals**
  ***Dixie B. Baker, Jane Kaye, and Sharon F. Terry***
  This peer-reviewed article presents the Fair Information Practice principles as a framework for data governance that respects the persons whose data are used while minimizing risk. Managing risk associated with information sharing and how the HIPAA privacy rule pertains to data governance are also discussed.

- [The Future of Patient Engagement in the Governance of Shared Data]
  ***Carolyn Petersen***
  This author's commentary "considers the evolving use of PHI in clinical care; explores key issues in provider-patient relationships that underlie data sharing; and describes an approach to PHI sharing that facilitates patient engagement, relationship building, and shared decision-making."

- [Sustained and Coordinated Efforts Could Facilitate Data Sharing While Protecting Privacy]
  ***United States Government Accountability Office***
  This report from the GAO reviewed data-sharing practices across human services organizations in different states and localities and recommends the federal government clarify and standardize privacy guidelines across programs. The GAO concluded that increased data-sharing increased the efficiency of human services operations and improved client outcomes yet state and local agencies face hurdles in addressing privacy concerns as they attempt to share data.

**Patient-Centered and Informed Consent**

- [Developing a Transparent, Participant-Navigated Electronic Informed Consent for Mobile-Mediated Research]
  ***Sage Bionetworks***
  Sage Bionetworks has developed a novel multi-media approach to addressing transparency and comprehension within electronic informed consent (eConsent) for app-mediated research studies. Here we describe the rationale for the framework selected and best practice for application of the framework in other clinical studies.

- [Participant Centered Consent Toolkit]
  ***Sage Bionetworks***
  The goal of the PCC toolkit is to transform the concept of consent from a signature on a legal form to a process that educates, and to allow as many people as possible to engage in consented studies. The material is openly licensed and may be used in any context, by any user, for any purpose, as long as attribution is provided back to Sage Bionetworks.

- [Enduring and Emerging Challenges of Informed Consent]
  ***Christine Grady***
  This peer-reviewed article provides an overview of informed consent in a medical context. It presents three emerging challenges related to establishing consent: newer models of clinical health care and clinical research that change the implications of consent, new technologies that change the context of consent, and changing demographics within the United States.

**EHR/HIE Consent**

- [Consumer Consent Options for Electronic Health Information Exchange: Policy Considerations and Analysis]
  ***Melissa Goldstein and Alison Rein for the Office of the National Coordinator for Health IT***
  This paper discusses the primary consent models associated with health information exchanges and electronic patient information. The authors present the issues and tradeoffs associated with various consent models, in particular mechanisms that encourage patient and provider utilization of the HIE system.

- [Health Information Exchanges Introduce Patient Consent Questions]
  ***Ken Terry***
  This author discusses meaningful consent around HIEs and practices for obtaining consent per different state regulations (opt-in, opt-out, blended or other). Issues with inconsistency in policies across states is also discussed.

- [Public Health Surveillance Data: Legal, Policy, Ethical, Regulatory, and Practical Issues]
  ***Amy B. Bernstein and Marie Haring Sweeney for the CDC***
  This report proposes a vision for improving access to and sharing of data useful for public health surveillance, identifies challenges and opportunities, and suggests approaches to attain the vision."

**Considerations for the Education Sector**

- **Privacy Technical Assistance Center Toolkit**
  ***US Department of Education, Privacy Technical Assistance Center (PTAC)***
  The PTAC has compiled best practice resources to help education stakeholders, including state and local education agencies, and postsecondary education partners involved in building and using education data systems, learn more about data privacy, confidentiality, and security practices related to student-level longitudinal data systems.

- **Data-Sharing Toolkit for Communities: How To Leverage Community Relationships While Protecting Student Privacy**
  ***US Department of Education***
  This toolkit is for organizations planning to use shared data to improve academic and quality of life outcomes for students while protecting their privacy. The authors simplify FERPA so that communities can understand the parameters for sharing personally identifiable information (PII) from education records.