



The Office of the National Coordinator for
Health Information Technology



Legal and Ethical Architecture for PCOR Data

APPENDIX D: SELECTED FEDERAL RESOURCES

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INTRODUCTION

This Appendix includes an overview of key federal agencies and guidance they have released relevant to PCOR and CER. For each agency, a description of the agency's authority is provided, as well as titles of and links to relevant guidance documents released by that agency. The guidance documents listed beneath each agency are listed in chronological order, with the most recent guidance listed first. Where a guidance document was developed and released in collaboration with one or more additional federal agencies, a parenthetical after the document title lists the other agencies involved. Guidance documents are listed under the agency that posted the document: where multiple agencies post the same document, it is listed under each agency. The date of the document is included where available or, if unavailable, the date listed on the website as the date the material was last reviewed is included. Some documents do not have date information and are listed at the bottom of the list of resources for each agency with a note indicating no date information is available.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

<https://www.cdc.gov/>

The Centers for Disease Control and Prevention (CDC) is a federal agency within the U.S. Department of Health and Human Services responsible for the protection of public health and the control of disease and injury. The CDC is responsible for conducting relevant research activities and collecting data on disease outbreaks.

- National Outbreak Reporting System (NORS) User Guidance—Waterborne Disease Outbreaks, February 2017. https://www.cdc.gov/nors/pdf/cdc_5212_guidance.pdf
- National Outbreak Reporting System Guidance—Foodborne Illness, February 2017. <https://www.cdc.gov/nors/downloads/guidance.pdf>
- HIPAA Privacy Rule and Public Health, April 2003. <https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

<https://www.cms.gov/>

The Centers for Medicare & Medicaid Services (CMS) is a federal agency within the U.S. Department of Health and Human Services responsible for the administration of Medicare and working with state governments to administer Medicaid and the Children's Health Insurance Program (CHIP).

- HIPAA Basics for Providers: Privacy, Security, and Breach Notification Rules, August 2016. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/HIPAAPrivacyandSecurityTextOnly.pdf>
- Covered Entity Decision Tool, June 2016. <https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/Downloads/CoveredEntitiesChart20160617.pdf>
- Security Standards: Implementation for the Small Provider, December 2007. <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/smallprovider.pdf?language=es>

- Basics of Risk Analysis and Risk Management, March 2007.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/riskassessment.pdf?language=es>
- Security 101 for Covered Entities, March 2007.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/security101.pdf?language=es>
- Security Standards: Administrative Safeguards, March 2007.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/adminsafeguards.pdf?language=es>
- Security Standards: Organizational, Policies and Procedures and Documentation Requirements, March 2007.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/pprequirements.pdf?language=es>
- Security Standards: Physical Safeguards, March 2007.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/physsafeguards.pdf?language=es>
- Security Standards: Technical Safeguards, March 2007.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/techsafeguards.pdf?language=es>

FEDERAL TRADE COMMISSION (FTC)

<https://www.ftc.gov/>

The Federal Trade Commission (FTC) is a federal agency responsible for the protection of consumers and their information and competition. In that role, they have released multiple materials that have been used to guide the efforts of other federal and state agencies, including the ONC. In particular, the FTC Fair Information Practice Principles (FIPPs) are widely cited. These principles resulted from the FTC's review of online entities that collect and use personal information to ensure that such efforts are fair and include appropriate privacy protections. The FIPPs address the following core elements related to information privacy: 1) notice to consumer prior to information collection; 2) choice/consent providing consumers' ability to control how their data is used (including opt-in and opt-out models); 3) limiting collection/use to stated purposes and enabling consumers to view and verify data collected; 4) transparency about information collected; 5) ensuring reasonable security protections; and 6) accountability for information and compliance with relevant laws and regulations.

- Mobile Health App Developers: FTC Best Practices, April 2016. <https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-app-developers-ftc-best-practices>
- Mobile Health Apps Interactive Tool (Developed with FTC, OCR, and ONC), April 2016.
<https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool>
- Medical Identity Theft: FAQs for Health Care Providers and Health Plans, January 2011.
<https://www.ftc.gov/tips-advice/business-center/guidance/medical-identity-theft-faqs-health-care-providers-health-plans>
- Copier Data Security: A Guide for Businesses, November 2010. <https://www.ftc.gov/tips-advice/business-center/guidance/digital-copier-data-security-guide-businesses>

FOOD AND DRUG ADMINISTRATION (FDA)

<https://www.fda.gov/>

The Food and Drug Administration (FDA) is a federal agency within the U.S. Department of Health and Human Services responsible for regulating pharmaceutical drugs, medical devices, dietary supplements, tobacco products, food safety, and vaccines among other things.

- Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 C.F.R. Part 11—Questions and Answers—Guidance for Industry, June 2017. <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm563785.pdf>
- FDA Medical Device Cybersecurity, March 2017. <https://www.fda.gov/MedicalDevices/DigitalHealth/ucm373213.htm>
- Use of Electronic Health Record Data in Clinical Investigations: Guidance for Industry, May 2016. <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm501068.pdf>
- Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff, February 2015. <https://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf>
- DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information—Guidance for Industry, November 2014. <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm424895.pdf>
- FDASIA Health IT Report (Developed by FDA, FCC and ONC), April 2014. <https://www.fda.gov/MedicalDevices/DigitalHealth/ucm338920.htm>
- Electronic Source Data in Clinical Investigations—Guidance for Industry, September 2013. <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm328691.pdf>
- Department of Health and Human Services Guidance Regarding Patient Safety Organizations' Reporting Obligations and the Patient Safety and Quality Improvement Act of 2005 (no date available). <https://www.hhs.gov/sites/default/files/PSQIAFDA2guidance.pdf>

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS (NCVHS)

- Recommendations on De-identification of Protected Health Information under HIPAA, February 2017. <https://www.ncvhs.hhs.gov/wp-content/uploads/2013/12/2017-Ltr-Privacy-DeIdentification-Feb-23-Final-w-sig.pdf>

NATIONAL INSTITUTES OF HEALTH (NIH)

<https://www.nih.gov/>

The National Institutes of Health (NIH) is a federal agency within the U.S. Department of Health and Human Services responsible for conducting biomedical and public health research. NIH is also responsible for awarding research grants to external researchers.

- Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research, June 2016. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>
- NIH Precision Medicine Initiative, “All of Us” (no date available). <https://allofus.nih.gov/>
- Sync for Science Pilot (Developed by NIH in coordination with ONC) (no date available). <http://syncfor.science/>
- Certificate of Confidentiality FAQs (no date available). <https://humansubjects.nih.gov/coc/faqs#eligibility>

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY (NIST)

<https://www.nist.gov/>

The National Institute of Standards and Technology (NIST) is a non-regulatory agency within the U.S. Department of Commerce; it is a measurement sciences laboratory. NIST also develops technology standards utilized by the federal government, including security standards for storing sensitive information such as personal health information.

- An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule, October 2008. <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/nist80066.pdf?language=es>

OFFICE FOR CIVIL RIGHTS (OCR)

<https://www.hhs.gov/ocr/index.html>

The Office for Civil Rights (OCR) is the federal agency within the U.S. Department of Health and Human Services responsible for enforcement of the HIPAA Privacy, Security, and Breach Notification Rules (see Appendix A for summaries of these rules). OCR has released guidance addressing: individuals’ right of access to their health information, privacy, and security guidance for electronic health records; guidance for health app developers; and tools and resources for HIPAA Regulated Entities. OCR enforcement action settlements also provide helpful guidance, particularly those related to medical devices and Internet applications.

- Fast Facts for Covered Entities, last reviewed on June 16, 2017. <https://www.hhs.gov/hipaa/for-professionals/covered-entities/fast-facts/index.html>
- Guidance on HIPAA & Cloud Computing, last reviewed on June 16, 2017. <https://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html>
- Privacy and Security Toolkit, last reviewed on June 16, 2017. <https://www.hhs.gov/hipaa/for-professionals/special-topics/health-information-technology/index.html>
- File Sharing and Cloud Computing: What to Consider?, June 2017. <https://www.hhs.gov/sites/default/files/june-2017-ocr-cyber-newsletter.pdf>
- My Entity Just Experienced a Cyber-attack! What Do We Do Now? A Quick-Response Checklist from the HHS, Office for Civil Rights (OCR), June 2017. <https://www.hhs.gov/sites/default/files/cyber-attack-checklist-06-2017.pdf>

- Cybersecurity Incidents Will Happen... Remember to Plan, Respond, and Report!, May 2017.
<https://www.hhs.gov/sites/default/files/may-2017-ocr-cyber-newsletter.pdf>
- Man-in-the-Middle Attacks and HTTPS Inspection Products, April 2017.
<https://www.hhs.gov/sites/default/files/april-2017-ocr-cyber-awareness-newsletter.pdf?language=es>
- Workshop on the HIPAA Privacy Rule's De-Identification Standard, last reviewed on March 28, 2017.
<https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/2010-de-identification-workshop/index.html>
- Reporting and Monitoring Cyber Threats, February 2017.
<https://www.hhs.gov/sites/default/files/february-2017-ocr-cyber-awareness-newsletter.pdf?language=es>
- Understanding the Importance of Audit Controls, January 2017.
<https://www.hhs.gov/sites/default/files/january-2017-cyber-newsletter.pdf?language=es>
- Guidance and Resources for Electronic Information Technology: Ensuring Equal Access to All Health Services and Benefits Provided through Electronic Means, December 2016.
<https://www.hhs.gov/sites/default/files/ocr-guidance-electronic-information-technology.pdf>
- Understanding DoS and DDoS Attacks and Best Practices for Prevention, November 2016.
<https://www.hhs.gov/sites/default/files/december-2016-cyber-newsletter.pdf?language=es>
- Sharing Consumer Health Information? Look to HIPAA and the FTC Act, October 2016.
<https://www.ftc.gov/tips-advice/business-center/guidance/sharing-consumer-health-information-look-hipaa-ftc-act>
- Mining More than Gold, October 2016. <https://www.hhs.gov/sites/default/files/ocr-october-2016-cyber-newsletter.pdf?language=es>
- Requirements of Title VI of the Civil Rights Act of 1964 (Developed with the Administration for Children and Families (ACF) and the U.S. Department of Justice (DOJ)), October 2016.
<https://www.hhs.gov/sites/default/files/title-vi-child-welfare-guidance-10-19-16.pdf>
- What Type of Authentication Is Right for You?, October 2016.
<https://www.hhs.gov/sites/default/files/november-2016-cyber-newsletter.pdf?language=es>
- Cyber Threat Information Sharing, September 2016. <https://www.hhs.gov/sites/default/files/hipaa-cyber-awareness-monthly-issue8.pdf?language=es>
- Do You Know Who Your Employees Are?, August 2016.
<https://www.hhs.gov/sites/default/files/Cyber-awareness-monthly-issue-7.pdf?language=es>
- Help Emergency Preparedness, Response, and Recovery Providers Comply with Title VI of the Civil Rights Act, (Developed with the U.S. Department of Housing and Urban Development (HUD), U.S. Department of Homeland Security (DHS), U.S. Department of Justice (DOJ), and U.S. Department of Transportation (DOT)). August 2016. <https://www.hhs.gov/sites/default/files/joint-guidance-titlevi-emergency-preparedness-august-2016.pdf>
- HIPAA Audit Guidance & FAQ on HIPAA and Unique Device Identifiers, July 2016.
<https://www.hhs.gov/sites/default/files/2016HIPAADeskAuditAuditeeGuidance.pdf>
- Fact Sheet: Ransomware and HIPAA, July 2016.
<https://www.hhs.gov/sites/default/files/RansomwareFactSheet.pdf>
- Is Your Covered Entity or Business Associate Capable of Responding to a Cybersecurity Incident?, July 2016. <https://www.hhs.gov/sites/default/files/HIPAA-cyber-awareness-monthly-issue-6.pdf?language=es>
- Guidance and Resources for Long Term Care Facilities, June 2016.
<https://www.hhs.gov/sites/default/files/mds-guidance-2016.pdf>

- What's in Your Third-Party Application Software?, June 2016.
<https://www.hhs.gov/sites/default/files/may-cyber-newsletter-05272016-final.pdf?language=es>
- Cyber Awareness Monthly Update May 3, May 2016. <https://www.hhs.gov/sites/default/files/hipaa-cyber-awareness-monthly-issue-4.pdf?language=es>
- Cyber-Awareness Monthly Update March 30, March 2016.
<https://www.hhs.gov/sites/default/files/hipaa-cyber-awareness-monthly-issue3.pdf?language=es>
- Cyber-Awareness Monthly Update March 3, March 2016.
<https://www.hhs.gov/sites/default/files/hipaa-cyber-awareness-monthly-issue2.pdf?language=es>
- Patient Electronic Access to Health Information, March 2016. https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2016_PatientElectronicAccess.pdf
- Cyber-Awareness Monthly Update February, February 2016.
<https://www.hhs.gov/sites/default/files/hipaa-cyber-awareness-monthly-issue1.pdf?language=es>
- HIPAA Security Rule Crosswalk to NIST Cybersecurity Framework, February 2016.
<https://www.hhs.gov/sites/default/files/nist-csf-to-hipaa-security-rule-crosswalk-02-22-2016-final.pdf>
- Questions and Answers about HIPAA's Access Right, last reviewed on February 25, 2016.
<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html#newlyreleasedfaqs>
- Understanding Some of HIPAA's Permitted Uses and Disclosures, last reviewed on February 12, 2016.
<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/permitted-uses/index.html>
- Individuals' Right under HIPAA to Access Their Health Information 45 C.F.R. § 164.524, January 2016.
<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>
- HIPAA FAQs for Professionals, last reviewed on September 9, 2015. <https://www.hhs.gov/hipaa/for-professionals/faq>
- HIPAA Privacy and Security and Workplace Wellness Programs, last reviewed on April 20, 2015.
<https://www.hhs.gov/hipaa/for-professionals/privacy/workplace-wellness/index.html>
- BULLETIN: HIPAA Privacy in Emergency Situations, November 2014.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/emergency/hipaa-privacy-emergency-situations.pdf>
- HIPAA: Public Health Authority Disclosure Request Checklist (Developed with the Assistant Secretary for Preparedness and Response (ASPR)), October 2014.
<https://www.hhs.gov/sites/default/files/hipaa-disclosure-chcklist102314.pdf>
- HIPAA Privacy Rule and Sharing Information Related to Mental Health, February 2014.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/mhguidancepdf.pdf>
- Sharing Information Related to Mental Health, February 2014.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/mhguidancepdf.pdf>
- Health Information of Deceased Individuals, last reviewed on September 19, 2013.
<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/health-information-of-deceased-individuals/index.html>
- Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule: A Guide for Law Enforcement (Developed with the U.S. Department of Justice (DOJ)), September 2013.
https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/emergency/final_hipaa_guide_law_enforcement.pdf

- Personal Representatives, last reviewed on September 19, 2013. <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/personal-representatives/index.html>
- The HIPAA Privacy Rule and Refill Reminders and Other Communications about a Drug or Biologic Currently Being Prescribed for the Individual, last reviewed on September 19, 2013. <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/refill-reminders/index.html>
- Student Immunizations, last reviewed on September 19, 2013. <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/student-immunizations/index.html>
- Is the HIPAA Privacy Rule Suspended during a National or Public Health Emergency?, last reviewed on July 26, 2013. <https://www.hhs.gov/hipaa/for-professionals/faq/1068/is-hipaa-suspended-during-a-national-or-public-health-emergency/index.html>
- Guidance on Significant Aspects of the Privacy Rule, June 2013. <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/significant-aspects/index.html>
- Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, November 2012. https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/De-identification/hhs_deid_guidance.pdf
- Guidance on Risk Analysis Requirements under the HIPAA Security Rule, July 2010. <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/rafinalguidance.pdf>
- Joint Guidance on the Application of the Family Educational Rights and Privacy Act (FERPA) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to Student Health Records, (Developed with the U.S. Department of Education (DOE)). November 2008. <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/hipaaferpaajointguide.pdf>
- HIPAA Security Guidance: Remote Use, December 2006. <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/remotese.pdf?language=es>
- HIPAA Privacy Rule Compliance Guidance and Enforcement Statement for Activities in Response to Hurricane Katrina, September 2005. <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/emergency/enforcementstatement.pdf>
- Hurricane Katrina Bulletin: HIPAA Privacy and Disclosures in Emergency Situations, September 2005. <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/emergency/katrinanhipaa.pdf>
- Summary of the HIPAA Privacy Rule, May 2003. <https://www.hhs.gov/sites/default/files/privacysummary.pdf>
- Business Associates, April 2003. <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/businessassociates.pdf>
- Disclosures for Public Health Activities, April 2003. <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/publichealth/publichealth.pdf>
- Disclosures for Workers' Compensation Purposes, April 2003. <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/workerscompensation.pdf>

- General Overview of Standards for Privacy of Individually Identifiable Health Information, April 2003.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/summary/overview.pdf>
- Marketing, April 2003.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/marketing.pdf>
- Minimum Necessary, April 2003.
https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/minimum_necessary.pdf
- Notice of Privacy Practices for Protected Health Information, April 2003.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/notice.pdf>
- Research, April 2003.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/research/research.pdf>
- Restrictions on Government Access to Health Information, April 2003.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/govtaccess.pdf>
- Standards for Privacy of Individually Identifiable Health Information, April 2003.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/summary/introduction.pdf>
- Uses and Disclosures for Treatment, Payment, and Health Care Operations, April 2003.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/sharingfortpo.pdf>
- Incidental Uses and Disclosures, December 2002.
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/incidental%26d.pdf>
- A Health Care Provider's Guide to the HIPAA Privacy Rule: Communicating with a Patient's Family, Friends, or Others Involved in the Patient's Care (no date available).
https://www.hhs.gov/sites/default/files/provider_ffg.pdf
- Frequently Asked Questions about Family Medical History Information (no date available).
<https://www.hhs.gov/sites/default/files/familyhealthhistoryfaqs.pdf>
- Frequently Asked Questions about the Disposal of Protected Health Information (no date available).
<https://www.hhs.gov/sites/default/files/disposalfaqs.pdf>
- HIPAA and Marriage: Understanding Spouse, Family Member, Marriage, and Personal Representatives in the Privacy Rule (no date available).
<https://www.hhs.gov/sites/default/files/hipaa-and-marriage.pdf>
- Privacy, Security, and Electronic Health Records (no date available).
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/consumers/privacy-security-electronic-records.pdf>
- Sharing Health Information with Family Members and Friends (no date available).
<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/consumers/sharing-family-friends.pdf>
- Your Health Information Privacy Rights (no date available).
https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/consumers/consumer_rights.pdf

OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP)

<https://www.hhs.gov/ohrp/>

The Office for Human Research Protections (OHRP) is a federal agency within the U.S. Department of Health and Human Services responsible for overseeing the protection of human participants involved in research that is conducted or supported by HHS. Specifically, OHRP provides guidance, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research. OHRP also supports the Secretary's Advisory Committee on Human Research Protections (SACHRP) (discussed below) that advises the HHS Secretary on issues of human participant protections. OHRP recently released revisions to the Common Rule that governs federally supported research involving human participants.

These changes become effective on January 19, 2018. See Appendix A for a summary of the Common Rule.

- 45 C.F.R. 46 (Common Rule) FAQs. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/fag/45-cfr-46/index.html>
- Clinical Data Registries—OHRP Correspondence (2015), June 2015. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/june-25-2015-letter-to-robert-portman/index.html>
- National Health Registry Activities and 45 C.F.R. part 46 (2011), October 2014. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/regarding-application-of-45-cfr-46-to-national-health-registry/index.html>
- National Health Registry Activities, OHRP, December 2011. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/december-29-2011-letter-to-dr-anthony-asher/index.html>
- National Health Registry Activities, OHRP, August 2011. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/august-11-2011-letter-to-dr-anthony-asher/index.html>
- Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards, March 2009. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html>
- Coded Private Information or Specimens Use in Research, Guidance, October 2008. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html>
- Issues to Consider in the Research Use of Stored Data or Tissues (1996, 1997), November 1997. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/issues-to-consider-in-use-of-stored-data-or-tissues/index.html>

Within the OHRP Office of the Director is:

Secretary's Advisory Committee on Human Research Protections (SACHRP)

<https://www.hhs.gov/ohrp/sachrp-committee/index.html>

The Secretary's Advisory Committee on Human Research Protections (SACHRP) provides expert guidance and recommendations to the HHS Secretary on matters pertaining to the protection of human participants research.

OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY (ONC)

<https://www.healthit.gov/>

The Office of the National Coordinator for Health Information Technology (ONC) is a part of the Office of the Secretary at the U.S. Department of Health and Human Services. ONC is at the forefront of the department's health IT efforts. Since its inception, ONC has focused on developing policy, programs, and initiatives designed to advance the interoperable exchange of electronic health information. These efforts have consistently addressed the important role that privacy and security play in any efforts involving the use, release, and exchange of health information.

- State Health IT Privacy and Consent Laws and Policies, July 2017. <https://www.healthit.gov/policy-researchers-implementers/state-health-it-privacy-and-consent-laws-and-policies>
- State Health IT Privacy and Consent Laws and Policies Dashboard, July 2017. <https://dashboard.healthit.gov/apps/state-health-it-privacy-consent-law-policy.php>
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SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

<https://www.samhsa.gov/>

The Substance Abuse and Mental Health Services Administration (SAMHSA) is a federal agency within the U.S. Department of Health and Human Services. SAMHSA leads public health efforts related to behavioral health, including substance abuse and mental health issues. Importantly for purposes of this project, SAMHSA recently released revisions to 42 C.F.R. Part 2 (Part 2), the federal regulations that govern the use and disclosure of substance abuse patient health records. These revisions became effective on February 17, 2017. See Appendix A for a summary of the Part 2 regulations.

- The Confidentiality of Alcohol and Drug Abuse Patient Records Regulation and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs, June 2004.
<https://www.samhsa.gov/sites/default/files/part2-hipaa-comparison2004.pdf>

U.S. DEPARTMENT OF VETERANS AFFAIRS (VA)

<https://www.va.gov/>

The Veterans Health Administration (VHA) is a component of the U.S. Department of Veterans Affairs that runs medical assistance programs for veterans through a network of hospitals and medical centers around the country. VA, especially VHA, are responsible for maintaining the electronic health records of all veterans who access their facilities and additionally have the ability to make some of that data available for research purposes.

- Revocation of HIPAA Authorization for Research, February 2017.
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<https://www.research.va.gov/resources/policies/guidance/CertificatesConfidentiality.pdf>
- VHA Handbook 1907.01—Health Information Management and Health Records, March 2015.
https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3088
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- Safeguarding Veterans' Personal Information (no date available).
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RESEARCH DATA ASSISTANCE CENTER (RESDAC)

<https://www.resdac.org/>

The Research Data Assistance Center (ResDAC) is a contractor to the Centers for Medicare & Medicaid Services (CMS) and provides free user data support to nonprofit, academic, and government researchers interested in studying Medicare and Medicaid data. Resources include guides to choosing the right data files, preparing data requests, and data analysis tips; a data availability table; CMS fee information; and data file record layouts.