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An Overview of Legal Issues in Data Sharing

Changing the Culture of Data Management and Sharing
A National Academies Workshop
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Data Privacy and Security Laws

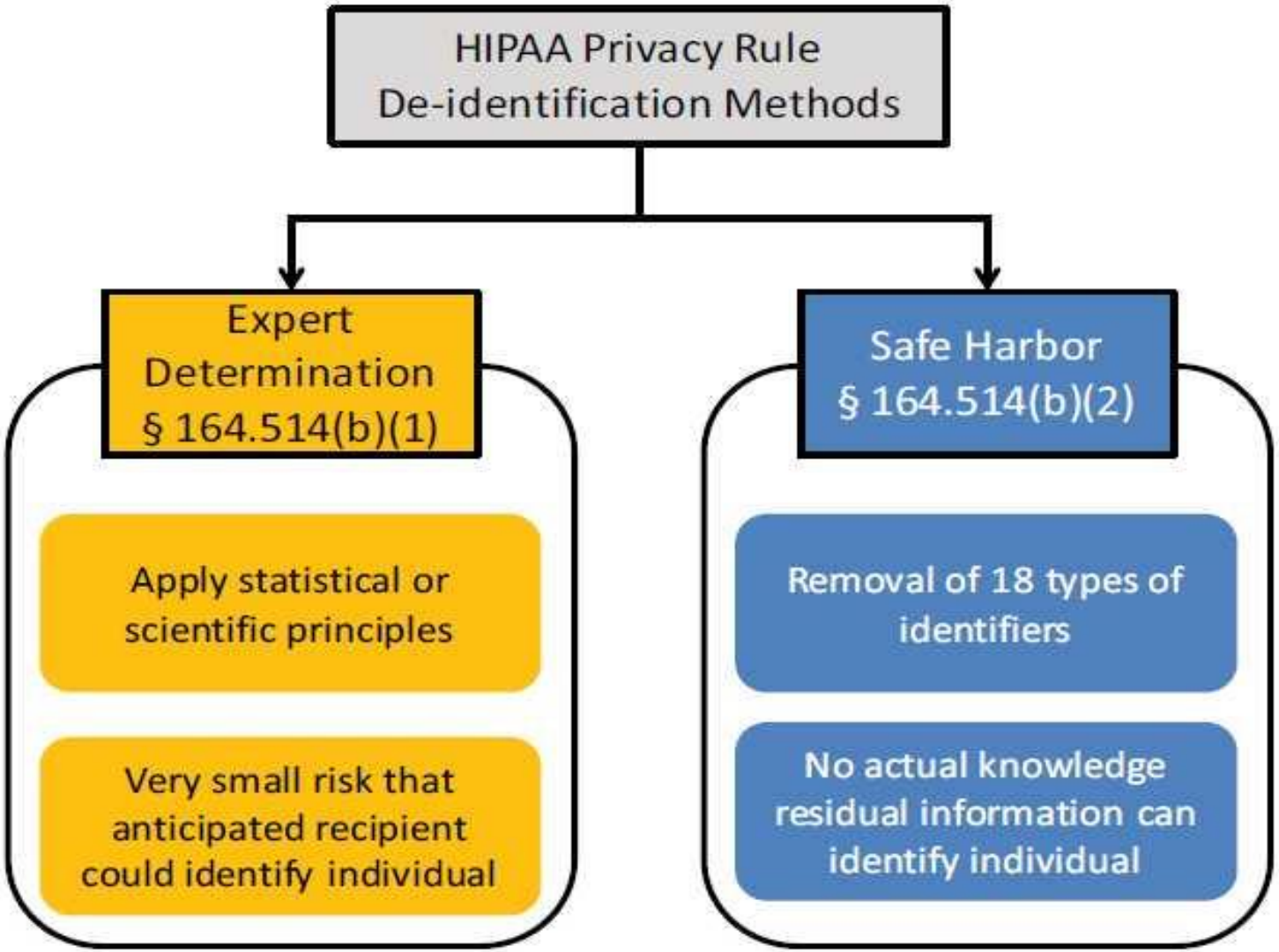
- US federal law
  - HIPAA
  - Federal substance use disorder treatment regulations (the "Part 2 regulations")
  - Common Rule
  - FDA regulations for clinical trials
  - NIH policies and grant requirements
- US state laws
  - Consumer privacy protection laws (e.g., the California Consumer Protection Act)
  - State health information confidentiality laws
  - State licensure requirements
- EU General Data Protection Regulation (GDPR) – and individual countries' laws throughout the world

Data Sharing Requirements

- Office of the National Coordinator for Health Information Technology (ONC) Interoperability and Information Blocking Rule
  - 85 Fed. Reg. 25642 (May 1, 2020), codified at 45 C.F.R. Parts 170 and 171
- Centers for Medicare and Medicaid Services (CMS) Interoperability and Patient Access Rule
  - 85 Fed. Reg. 25510 (May 1, 2020), codified at 42 C.F.R. Parts 406, 407, 422, 423, 431, 438, 457, 482, 485 and 45 C.F.R Part 156
- Intent of both rules:
  - To make patient data requests easy and inexpensive
  - To allow health care providers to move between health IT vendors and utilize health IT solutions of their choosing
  - To promote interoperability and use of electronic health information for purposes permitted by applicable law

Other Legal Issues in Data Sharing

- Data ownership/authority to share
  - Institutional data governance
  - Third party contractual rights
- Intellectual property
- Antitrust compliance
- Stark Law/Anti-kickback Statute compliance
- Regulations affecting downstream use (e.g., FDA regulation of AI)

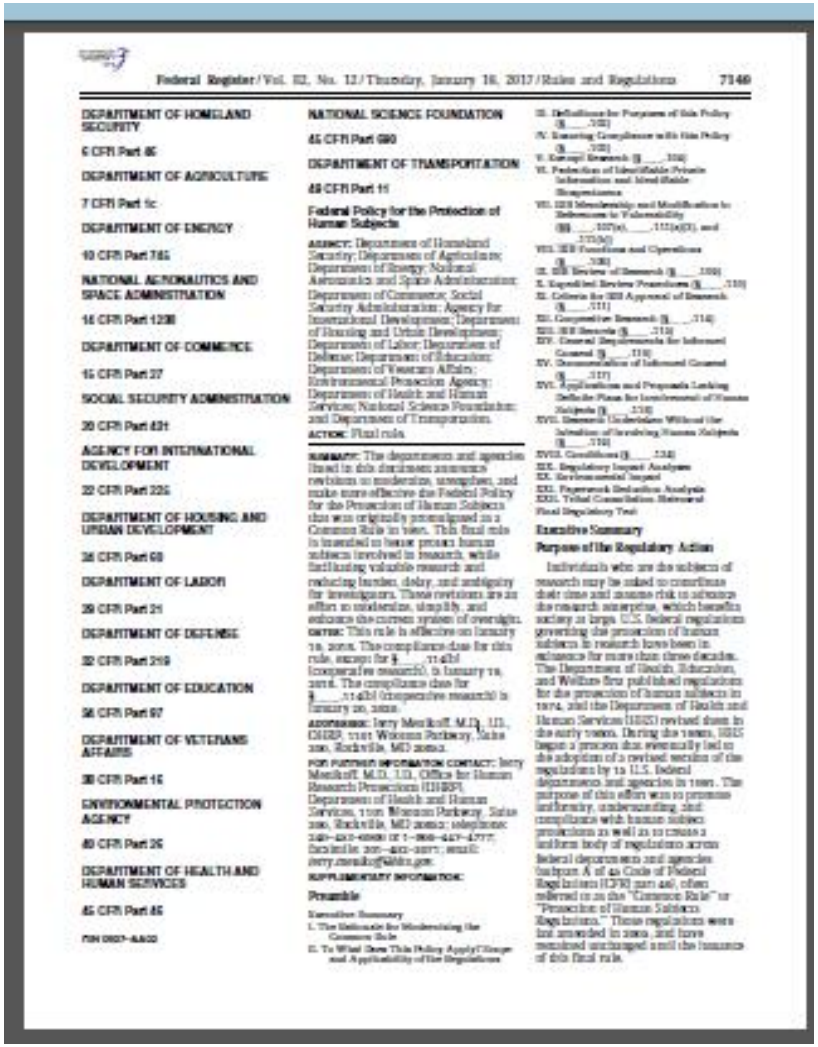


From Office for Civil Rights Guidance on De-Identification (11/26/12)
https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/De-identification/hhs_deid_guidance.pdf

HIPAA De-Identification

- Is genetic information Protected Health Information (PHI)?
  - Genetic information is "health information"
  - Health information is PHI if it is "individually identifiable information": it identifies the individual or "there is a reasonable basis to believe the information can be used to identify the individual"
  - Office for Civil Rights (OCR) has concluded that not all genetic information is "individually identifiable," but has not provided guidance on when genetic information is individually identifiable
  - Common interpretation: genetic information is not PHI unless it is accompanied by HIPAA identifiers or unless you know recipient has the ability to link the genetic information to a person's identity

The Revised Common Rule



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DEPARTMENT OF HOMELAND SECURITY

6 CFR Part 46

DEPARTMENT OF AGRICULTURE

7 CFR Part 1c

DEPARTMENT OF ENERGY

10 CFR Part 745

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1230

DEPARTMENT OF COMMERCE

15 CFR Part 27

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 431

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 225

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 60

DEPARTMENT OF LABOR

29 CFR Part 21

DEPARTMENT OF DEFENSE

32 CFR Part 219

DEPARTMENT OF EDUCATION

34 CFR Part 97

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 16

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 26

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

RIN 0937-AA02

NATIONAL SCIENCE FOUNDATION

45 CFR Part 690

DEPARTMENT OF TRANSPORTATION

49 CFR Part 11

Federal Policy for the Protection of Human Subjects

AGENCY: Department of Homeland Security; Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Social Security Administration; Agency for International Development; Department of Housing and Urban Development; Department of Labor; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; and Department of Transportation.

ACTION: Final rule.

SUMMARY: The departments and agencies listed in this document announce revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects (also originally promulgated as a Common Rule in text). This final rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. These revisions are an effort to modernize, simplify, and enhance the current system of oversight.

DATES: This rule is effective on January 19, 2018. The compliance date for this rule, except for §___.114(b) (cooperative research), is January 19, 2018. The compliance date for §___.114(b) (cooperative research) is January 20, 2020.

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FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Office for Human Research Protections (OHRP), Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; telephone: 240–453–6900 or 1–866–447–4777; facsimile: 301–402–2071; email: jerry.menikoff@hhs.gov.

SUPPLEMENTARY INFORMATION:

Preamble

Executive Summary

I. The Rationale for Modernizing the Common Rule

II. To What Does This Policy Apply? Scope and Applicability of the Regulations

III. Definitions for Purposes of this Policy (§___.102)

IV. Ensuring Compliance with this Policy (§___.103)

V. Consent Requirements (§___.116)

VI. Protection of Identifiable Private Information and Identifiable Biospecimens

VII. IRB Membership and Modifications to Submissions to Enhance Protections (§§___.107(a), ___.115(a)(3), and ___.115(b))

VIII. IRB Functions and Operations (§___.108)

IX. IRB Review of Research (§___.109)

X. Expedited Review Procedures (§___.110)

XI. Criteria for IRB Approval of Research (§___.111)

XII. Cooperative Research (§___.114)

XIII. IRB Records (§___.115)

XIV. General Requirements for Informed Consent (§___.116)

XV. Documentation of Informed Consent (§___.117)

XVI. Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects (§___.118)

XVII. Research Undertaken Without the Intention of Involving Human Subjects (§___.119)

XVIII. Clarifications (§___.124)

XIX. Regulatory Impact Analysis

XX. Environmental Impact

XXI. Paperwork Reduction Analysis

XXII. Tribal Consultation Statement

Final Regulatory Text

Executive Summary

Purpose of the Regulatory Action

Individuals who are the subjects of research may be asked to contribute their time and assume risk to advance the research enterprise, which benefits society at large. U.S. federal regulations governing the protection of human subjects in research have been in existence for more than three decades. The Department of Health, Education, and Welfare first published regulations for the protection of human subjects in 1974, and the Department of Health and Human Services (HHS) revised them in the early 1980s. During the 1980s, HHS began a process that eventually led to the adoption of a revised version of the regulations by 15 U.S. federal departments and agencies in 1991. The purpose of this effort was to promote uniformity, understanding, and compliance with human subjects protections as well as to create a uniform body of regulations across federal departments and agencies (subpart A of 45 Code of Federal Regulations (CFR) part 46, often referred to as the "Common Rule" or "Protection of Human Subjects Regulations." These regulations were last amended in 2005, and have remained unchanged until the issuance of this final rule.

- Applies to federally-funded research in the US
- Significant changes
  - **Potential changes to "identifiability"**
  - New HIPAA exemption
  - New requirements for informed consent
  - New exemption for research with "broad consent"
  - New exemption for publicly available information
  - New rule for preparing for research
  - New rule on single IRB for collaborative research

"Identifiability" May Change over Time

- Requires agencies to assess within one year of final rule whether there are technologies or techniques that should be considered to generate identifiable private information, even if not accompanied by traditional identifiers (such as whole genome analysis)
- May widen difference in interpretation of "non-identified" information under Common Rule (i.e., investigator cannot readily ascertain identify of research participants) and "de-identified" under HIPAA

State Laws

- State genetic information laws
  - Some laws apply to de-identified information
  - Some laws make genetic information the "property" of the individual
- State consumer privacy laws having a greater impact
  - California Consumer Privacy Act amended to use HIPAA de-identification standard (at least for data derived from PHI)
  - Virginia Consumer Privacy Act
  - More state laws on the way!

GDPR

- Any data that directly or indirectly identifies a living person (not just patients)
  - Name, identification number, location data, online identifiers, factors specific to the physical, psychological, genetic, mental, economic, cultural or social identity
- More sensitive data have special protection
  - Genetic data, biometric data for the purpose of creating unique identification, data concerning health, data regarding race, religion, politics, sex
- Treatment of de-identified data
  - No de-identification "safe harbor"– data is "anonymized" if under a "facts and circumstances" test, the data cannot be identified by any means "reasonably likely to be used … either by the controller or by another person"
  - "Pseudonymised" (coded) still personal data

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THANK YOU!

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