The Consent Paradox: the 2018 Common Rule Revisions Leave HIPAA-Covered Researchers in the Dark

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Background

In January 2017, 16 federal agencies revised the Federal Policy for the Protection of Human Subjects otherwise known as the Common Rule. The revision includes a new exemption permitting researchers regulated by the Health Insurance Portability and Accountability Act (HIPAA) to use identifiable private information for research without individual consent.

Methods

We utilized legal research methods and cannons of legal interpretation to synthesize how the revised federal Common Rule regulations apply in different research scenarios involving the new HIPAA regulated research exemption. Analysis and conclusions are informed by existing federal agency guidance. We use graphical flowcharts to depict our analysis.

Conclusion

The revised Common Rule creates a consent paradox. The paradox is present when a HIPAA-regulated researcher relies on 1) a "minimum necessary" HIPAA research disclosure, and 2) the new Common Rule HIPAA exemption. For research in the consent paradox, the Common Rule exempts research regulated by HIPAA from IRB review, but HIPAA requires a Common Rule IRB to review the research for a waiver of informed consent.

HIPAA-regulated researchers are bound by HIPAA's requirements for use and disclosure of protected health information. HIPAA permits two types of disclosures for research use: disclosure of a limited data set (no consent required with a data use agreement), and disclosure of the minimum necessary information for the research without consent. HIPAA usually requires consent for "minimum necessary" disclosures, but permits a Common Rule IRB to waive or alter the consent requirement for research purposes.

The revised Common Rule contains a new provision that exempts HIPAA regulated research. In other words, the revised Common Rule permits HIPAA-regulated researchers to use identifiable private information and identifiable biospecimens for secondary data research without following Common Rule informed consent requirements. However, HIPAA requires IRBs to review the research to determine whether a waiver of consent is appropriate. Consequently, the Common Rule HIPAA exemption permitting secondary data research without consent, in some cases, requires an IRB to review the research to see whether the a consent waiver is appropriate.

Limitations

This analysis focuses on new regulations that have yet to be implemented and lack particularized guidance. Other federal guidance is persuasive to courts, but not legally binding. Reasonable minds will sometimes differ in legal analysis. This material is intended to be educational and is not a substitute for legal advice.

Discussion

Big data is commonly used is most sectors. Yet there are still barriers to leveraging it for research due to concerns about information privacy. The revised Common Rule, going into effect in 2018, better facilitates research using big data by introducing multiple new exempt categories including the HIPAA exemption. Federal agencies adopted this new exemption with the recognition that HIPAA provides adequate safety protections. However, this new Common Rule exemption does not fit perfectly in the HIPAA regulatory framework and creates an apparent paradox. The new Common Rule exemption for secondary data studies by HIPAA-covered researchers needs more federal guidance.

References

HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46.104 (eff. 2018)

Federal Policy for the Protection of Human Subjects, 82 FR 7149-01 (Jan 2017)

HIPAA Privacy Rule, 45 C.F.R. §§ 164.512, 514

HIPAA

45 C.F.R. § 164.512(i)(1)

"A covered entity may use or disclose protected health information for research… provided that:

(i) Board approval of a waiver of authorization. **The covered entity obtains documentation that an alteration to or waiver…of the individual authorization** … has been approved by either:

(A) An Institutional Review Board (IRB), established in accordance with [the Common Rule §__.107]…"

Revised Common Rule

45 C.F.R. § 46.104(d)

"Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy:…

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: …

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information **when that use is regulated under [HIPAA],** for the purposes of … 'research'" (Effective 2018)

Common Rule - 45 C.F.R. 46.104(d)(4)(iii) Exemption for Secondary Research for which consent is not required

Exempts research from Common Rule requirements if research…

Involves Identifiable Private Information

Is secondary research

Is regulated by HIPAA

HIPAA Research Disclosure Provisions

then

Consent Paradox

Limited Data Set Research Disclosure 45 C.F.R. § 164.514(e)

Requires

Data Use Agreement

No Consent Required

Minimum Necessary Research Disclosure 45 C.F.R. § 164.512(i)

Requires

Informed Consent (Common Rule)

Or

IRB Alteration of Informed Consent (Common Rule)

Or

IRB Waiver of Informed Consent (Common Rule)

HIPAA Requires Consent But Common Rule - 45 C.F.R. 46.104(d)(4)(iii) Does not require consent

Research is Exempt from Common Rule Requirements

No Consent Required

Common Rule Exempts Research Without Consent if Researchers Regulated by HIPAA

HIPAA Requires Common Rule IRB Review and Might Require Consent

HIPAA Requires Common Rule IRB Review But Common Rule Exempts Research From Common Rule Requirements