

COFFEE COMPLIANCE &
CONVERSATIONS:
PRIVACY &
CONFIDENTIALITY OF DATA



Agenda

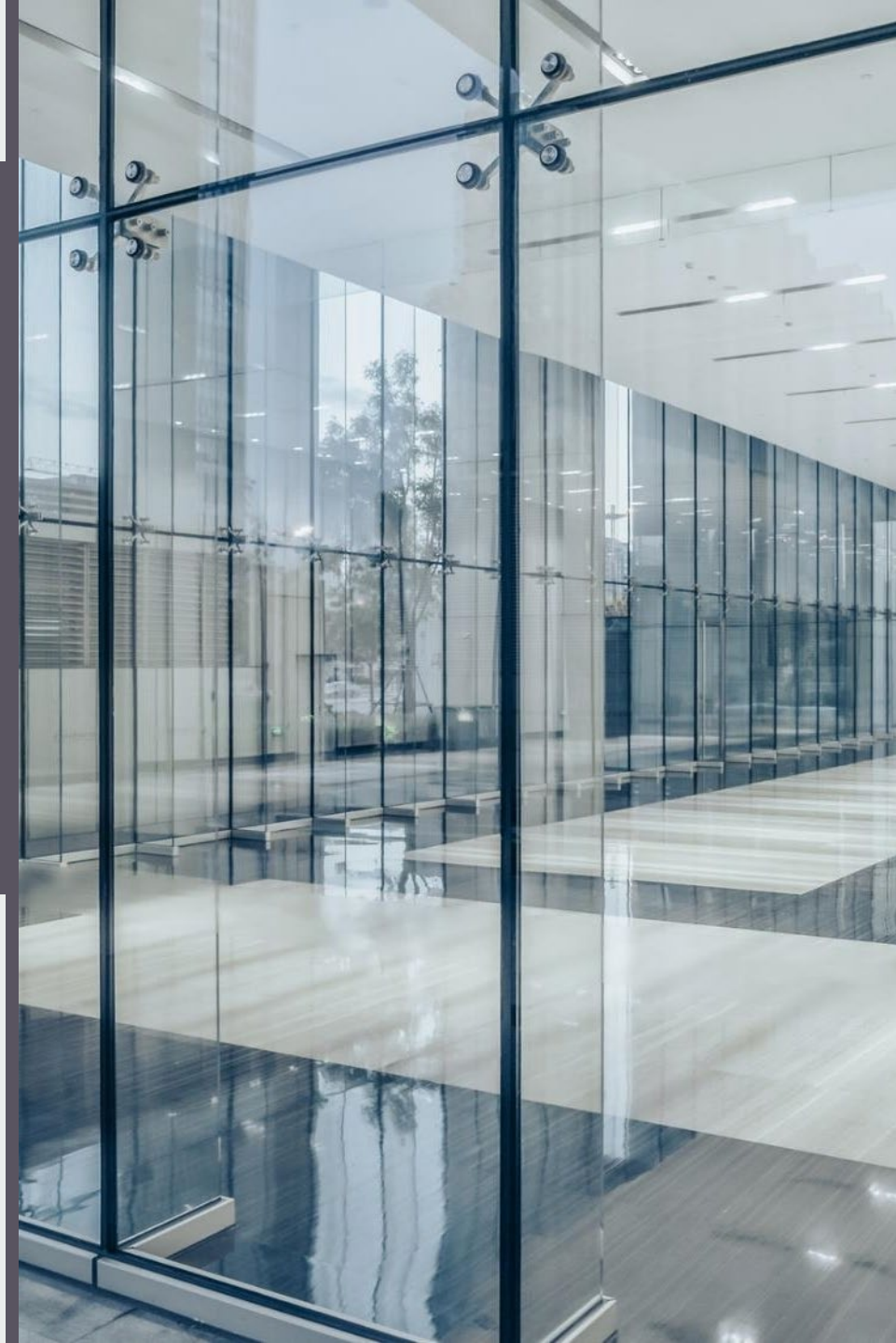
Review Regulations

Case Study Discussion

Tips

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RESEARCH COMPLIANCE REGULATIONS





U.S. Department of
Health and Human Services

Enhancing the health and well-being of all Americans

A covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

45 CFR 164.508(a)(1)




U.S. Department of
Health and Human Services

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A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that the covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by § 164.508 for use or disclosure of protected health information has been approved by an IRB or Privacy Board.

45 CFR 164.512(i)(1)(i)

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- Names
 - Phone numbers
 - Fax numbers
 - Email addresses
 - Social Security numbers (including scrambled SSNs)
 - Medical record numbers
 - Health plan beneficiary numbers
 - Account numbers
 - Certificate/license numbers

IDENTIFIERS

- Vehicle identifiers & serial numbers including license plate numbers
- Device identifiers & serial numbers
- URLs
- IP addresses
- Biometric identifiers, including finger & voice prints
- Full face photographic images & any comparable images
- All geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial 3 digits of a zip code

IDENTIFIERS

- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death
- Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

IDENTIFIERS



U.S. Department of
Health and Human Services

Enhancing the health and well-being of all Americans

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

45 CFR 46.111(a)(7)



FDA

21 CFR 56.111(a)(7)

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.



ICH GCP 1.6



The confidentiality of information that could identify participants should be protected in accordance with applicable privacy and data protection requirements.



ICH GCP 2.12.7

The investigator/institution should implement appropriate measures to protect the privacy and confidentiality of personal information of trial participants in accordance with applicable regulatory requirements on personal data protection. Data reported to the sponsor should be identified by an unambiguous participant code that can be traced back to the identity of the participant by the investigator/institution.





SAFEGUARDS





- Use the minimum necessary to address aims of study
- Store data/documents in a secure manner
- Control & limit access
- Code data






- PHI was disclosed to a researcher without the individual's HIPAA authorization or a waiver of HIPAA authorization.
- Lack of administrative and technical safeguards allowed for unauthorized access to private information

MOST COMMON INSPECTION FINDINGS






Cardiologist wants preliminary data for grant submission. Asks office administrator for list of patients from the electronic medical record to include the following data for each patient:


- MRNs
- Date of Birth
- Patient Name
- Street Address
- Phone #
- Email Address
- Insurance Status
- Dates of Hospitalization
- Reason for Hospitalization
- Drug Screening Results
- Medication List
- Dates of Clinic Visits
- Co-Morbidities

PRIVACY & CONFIDENTIALITY OF DATA



Colleague at UCLA is doing similar study. He wants to compare his data with patient data from the cardiologist's clinic. The cardiologist sends him the spreadsheet she got from the assistant that she saved on her personal laptop.

PRIVACY & CONFIDENTIALITY OF DATA



Cardiologist analyzing data at home on her personal laptop. Encounters issues with statistical analysis program. Daughter comes over to assist. Daughter recognizes several names as former classmates. One she is surprised to see was hospitalized for a heroin overdose. Daughter attends high school reunion and shares what she learned about their classmate. Classmate overhears and contacts the hospital.

PRIVACY & CONFIDENTIALITY OF DATA



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- Conducted research without prior IRB approval
- Accessed/Collected/Disclosed PHI for research purposes without HIPAA authorization/waiver
- Data was not stored appropriately
- Inappropriate access/disclosure of PHI
- No data use agreement was executed

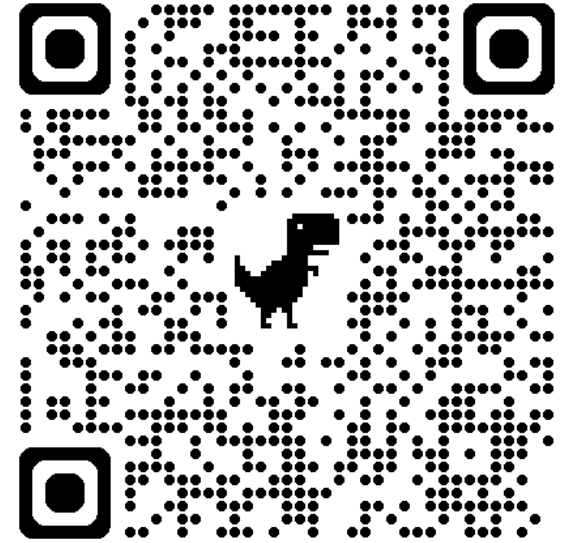
Tips

- Appropriate storage (ie: locked cabinet, Human Research Box)
- Limit access to only authorized personnel
- Use codes stored separately from data
- Use minimum data necessary
- Stop and Think!!!



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THANK YOU



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