

Health Insurance Portability and Accountability Act

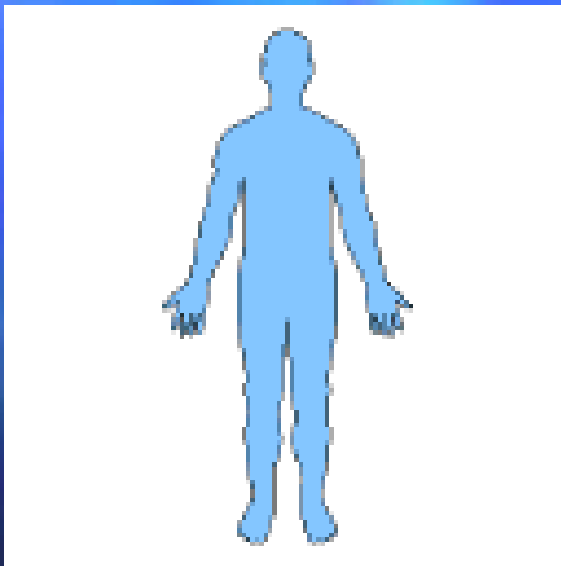
What Impact Does HIPPA Have on Human Subjects Research?

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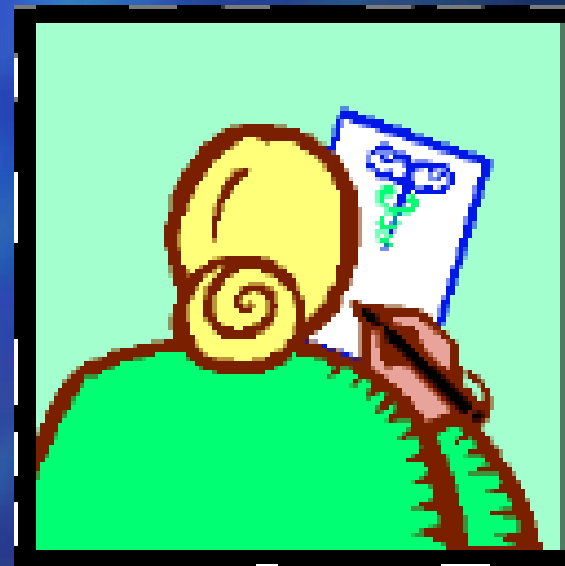
HIPPA and Human Subjects Research

What happens to my body?



The Common Rule

What happens to my information?



HIPAA

HI PPA and Human Subjects Research



**What is
Research?**

HI PAA defines research:
A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to *generalizable knowledge*

HIPAA and Human Subjects Research

- ✓ HIPAA has specialized rules applicable to research activities
- ✓ HIPAA requirements are applicable regardless of funding source
- ✓ Research disclosures must be included in the health care provider's (i.e., covered entity) "Notice of Information Practices"
- ✓ Patient authorization for research is not the same as informed consent. Authorizations are solely for privacy issues – they do not address risks of research treatment.

HI PPA and Human Subjects Research

- ✓ Covered entity must disclose in authorization if it will receive direct or indirect payment from a third party in exchange for the use of Protected Health Information (PHI).
- ✓ Requires that study sponsors and/or PI's research staff or related entities be named as parties to whom or to which PHI will be transferred
- ✓ FDA regulations already require that the FDA be named as patient consent forms as a party who may view medical information

Patient Authorization Not Required When:

- If PHI is used for research planning purposes (i.e., to recruit patients or formulate a research hypothesis).
 - ✓ Must demonstrate uses are necessary for research and will be used solely for narrow purposes, and
 - ✓ Must not remove PHI from covered entity
- If research is on decedents
- If a "Waiver of Authorization" is obtained from either an IRB or Privacy Board

Waiver of Patient Authorization



Institutional Review Board
Or
Privacy Board

- Privacy Board is similar to an IRB, but used for privacy issues
- Many of the same membership/voting requirements for IRBs are applicable to a Privacy Board

Waiver of Patient Authorization



**Institutional Review Board
Or
Privacy Board**

- May use existing IRBs, or form new Privacy Boards
- Review of Waiver may be done by expedited review
- Most likely to be used in chart review research

Waiver of Patient Authorization

Eight Criteria for Approval

1. Use of PHI involves minimal risk to subject
2. Waiver will not adversely affect privacy rights of individuals
3. Research could not be conducted without waiver
4. Research could not be conducted without access to PHI

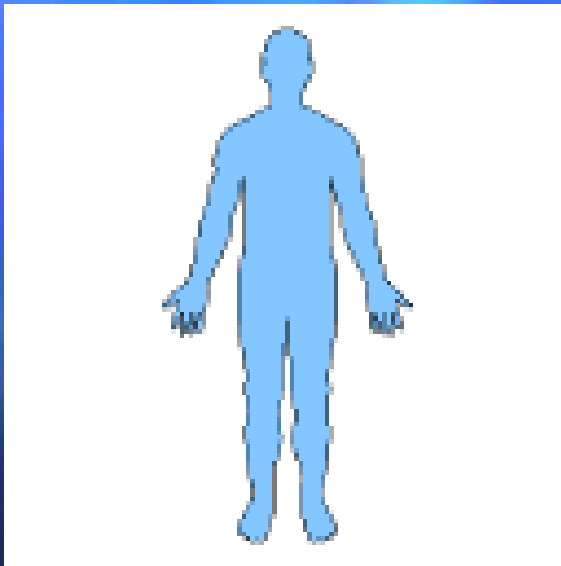
Waiver of Patient Authorization

Eight Criteria for Approval

5. Privacy risk/benefit ratio reasonable; and the resulting knowledge important
6. Adequate plan to protect identifiers from improper use and disclosure
7. Adequate plan to destroy identifiers at earliest opportunity, unless there is a health or research justification for retaining identifiers
8. Adequate written assurance that PHI will not be reused or disclosed to any other person or other research project

Waiver of Patient Authorization

Waiver of
Informed Consent



The Common Rule



Waiver of
Authorization



HIPAA

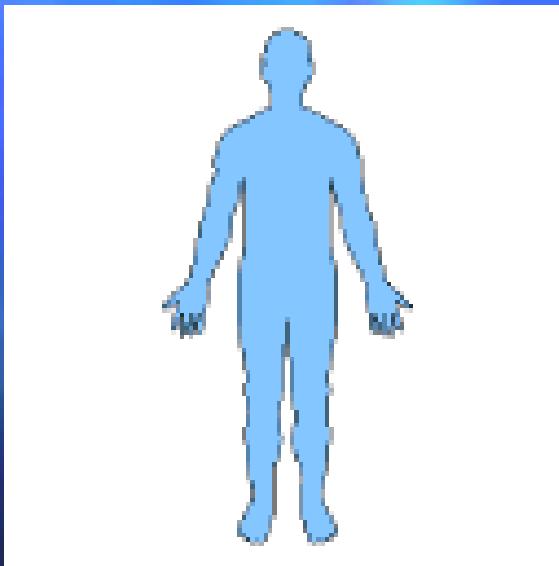
Waiver of Patient Authorization



Waiver of Informed Consent
vs.
Waiver of Authorization

- Two distinctly different processes
- Different criteria with significantly varying foci
- Require different methods of review

HIPPA and Human Subjects Research



The Common Rule

HIPAA



HI PPA and Human Subjects Research

Scenario 1

- The Chair of Emergency Services wants to review PHI data from his hospital medical records to evaluate ER access and utilization.
- He wishes to determine the overall percentage of indigent patients seeking ER services, as well as the average amount of time spent on indigent care by ER staff.
- His goal is to determine if this ER access by this population of individuals is the same as paying patients, and if not, how might he improve the services of his ER for these patients.

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Scenario 2

- A family practice resident is planning a research project that will evaluate utilization of ER services by the indigent population of her community.
- She asks medical records of her local hospital if she may see the records of patients attending the ER for the past 2 months.
- She informs the hospital that her purpose for this review is to accumulate PHI necessary for her to write her research proposal, and that she will not remove any PHI .

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Scenario 3

- Investigator wants to receive information including patient's name, SSN and zip code, from 2 area hospital's ERs.
- Investigator plans to merge these two databases into one single database.
- Investigators wants to know how many times individuals sought ER services from all hospitals to gain knowledge on access, utilization, etc.
- Investigator plans to share the findings with the hospitals, and also plans to publish his findings in a leading medical journal.