

Variability in the Implementation of HIPAA Policy



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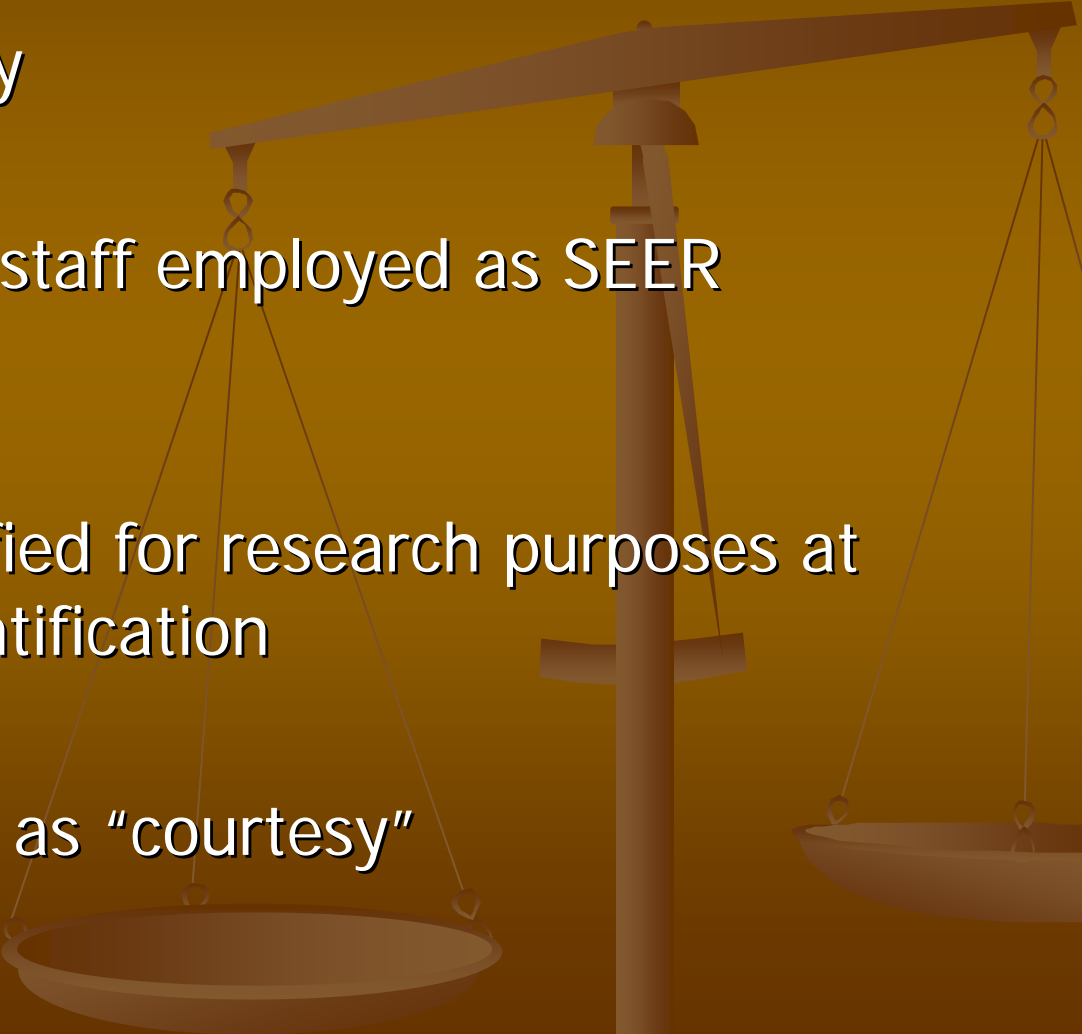


Cause: HIPAA Interpreted by Local IRBs

Result: Variability

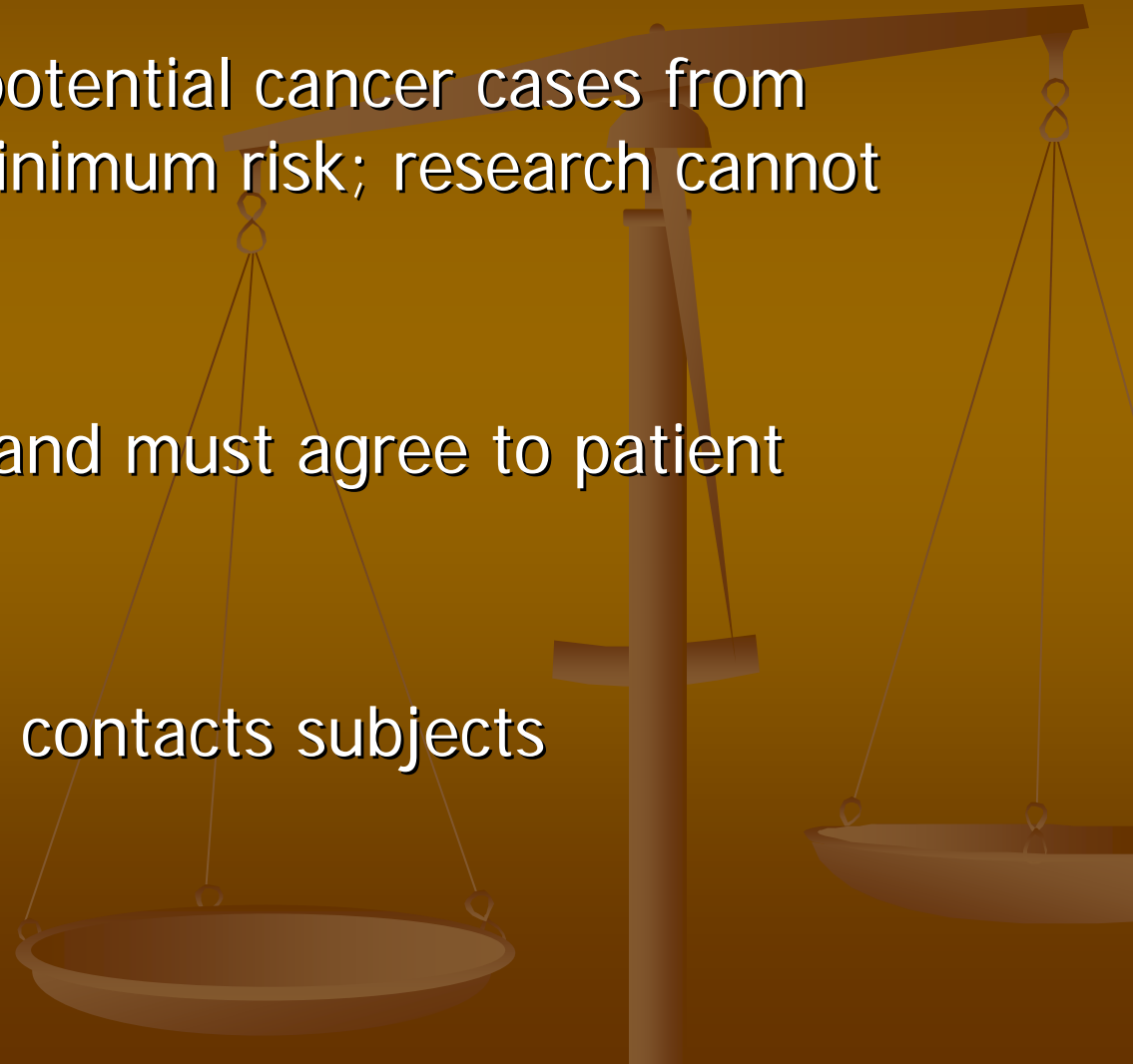


Stories: Karmonas (Detroit)

- ❖ SEER cancer registry
 - ❖ Karmonas research staff employed as SEER registrars
 - ❖ Cancer cases identified for research purposes at time of registry identification
 - ❖ Physician contacted as "courtesy"
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Stories: Yale

- ❖ Waiver to identify potential cancer cases from medical records “minimum risk; research cannot otherwise be done”
- ❖ Physicians notified and must agree to patient contact
- ❖ Research staff then contacts subjects



Stories: Science

Science magazine

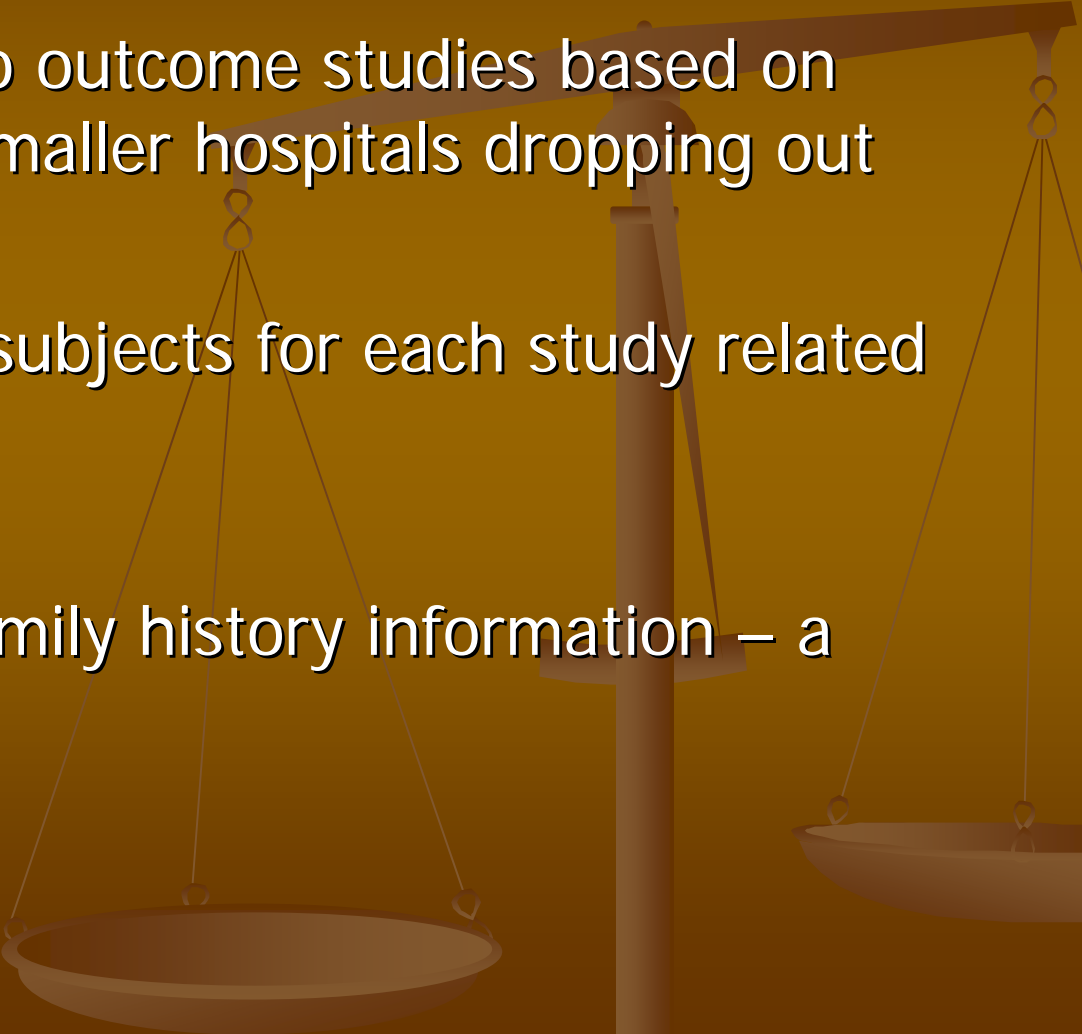
PATIENT RECORDS:

Privacy Rule Creates Bottleneck for U.S. Biomedical Researchers


Jocelyn Kaiser

A complicated new regulation is hindering a broad swath of science, from population-based and genetics studies to tissue repositories

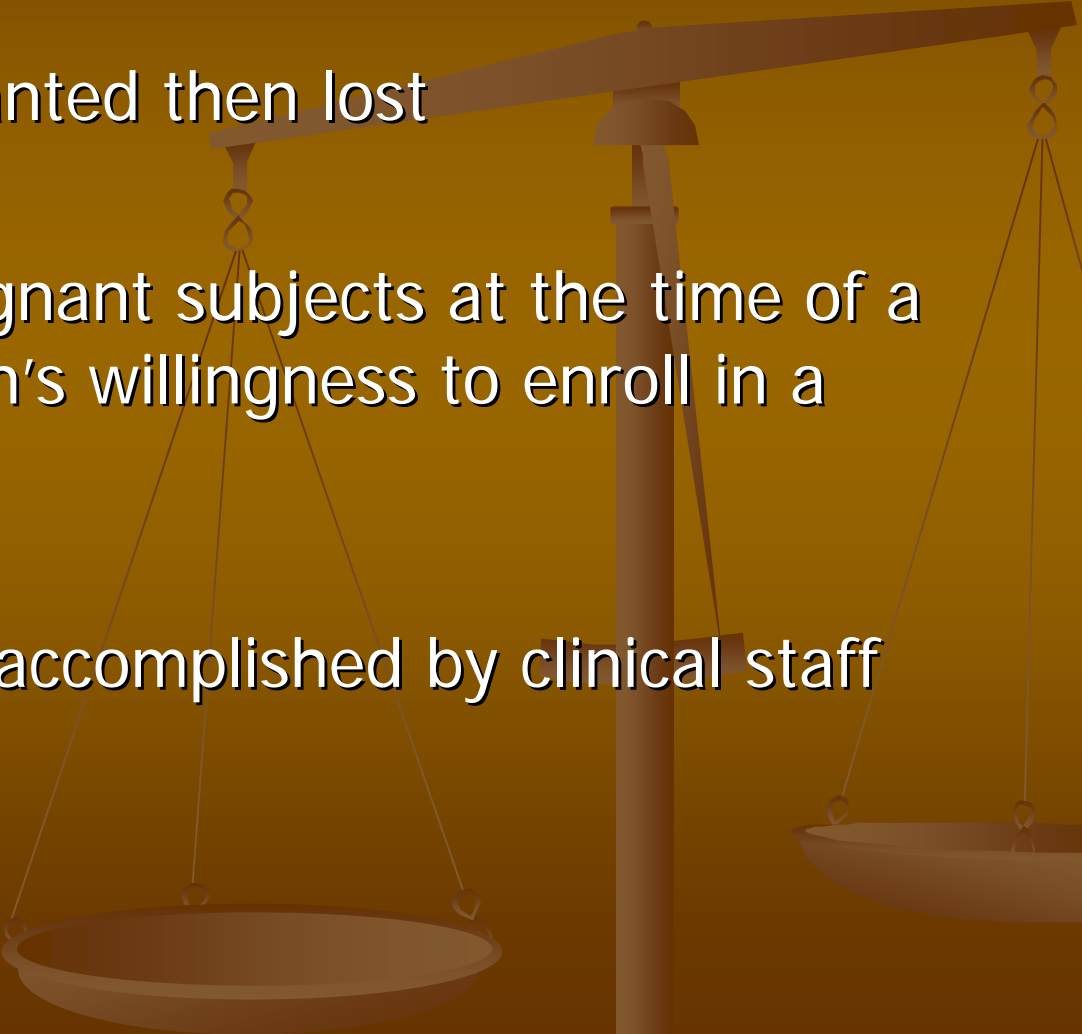
Stories: Science

- ❖ Limiting ability to do outcome studies based on medical records – smaller hospitals dropping out
 - ❖ Need to re-contact subjects for each study related to stored tissue
 - ❖ Genetic data and family history information – a question
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Stories: University of Pittsburgh

- ❖ Waivers generally not granted
 - ❖ Identification of cancer cases must come from individual treating physicians
 - ❖ Physician must contact patient prior to research staff contact
- 

Stories: University of Pittsburgh (2)

- ❖ Waiver originally granted then lost
 - ❖ Identification of pregnant subjects at the time of a visit relies on women's willingness to enroll in a research registry
 - ❖ Registry enrollment accomplished by clinical staff
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Impact on Pregnancy Cohort Recruitment

1998-2002:

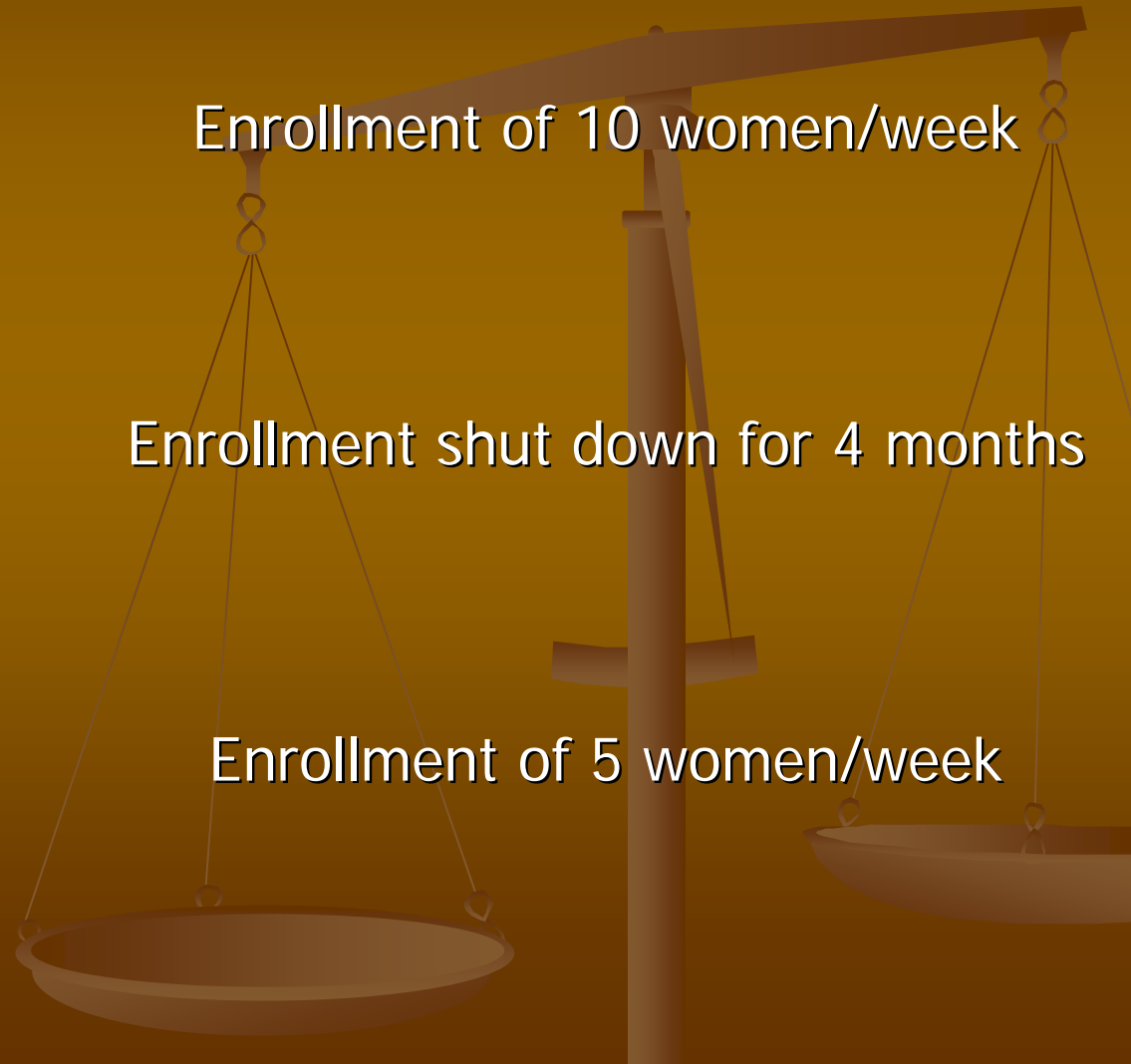
Enrollment of 10 women/week

2003 Jan-April:

Enrollment shut down for 4 months

April 2003-present:

Enrollment of 5 women/week



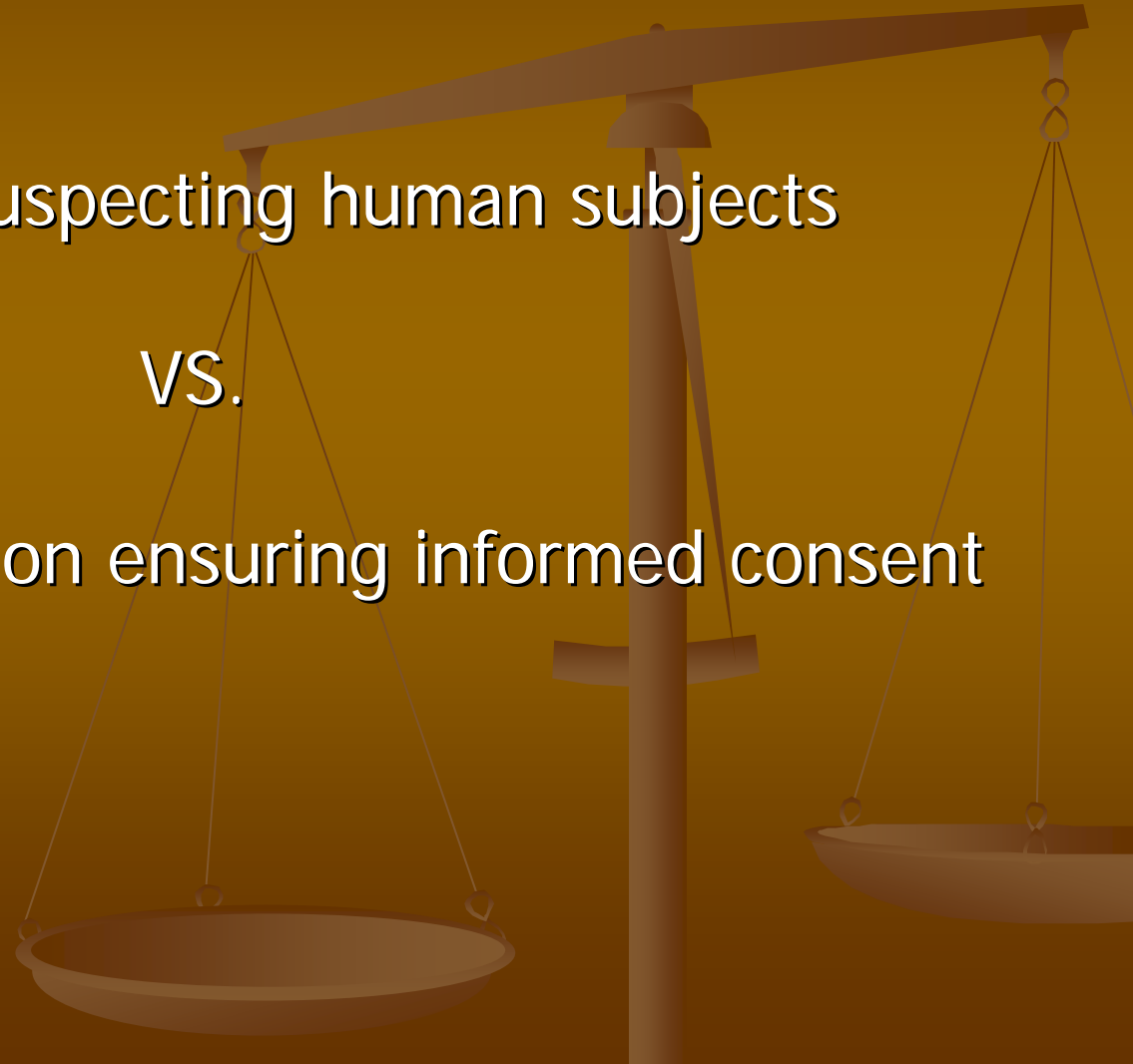
Underling Issues

IRB Philosophies

❖ Protectors of unsuspecting human subjects

VS.

❖ Service organization ensuring informed consent



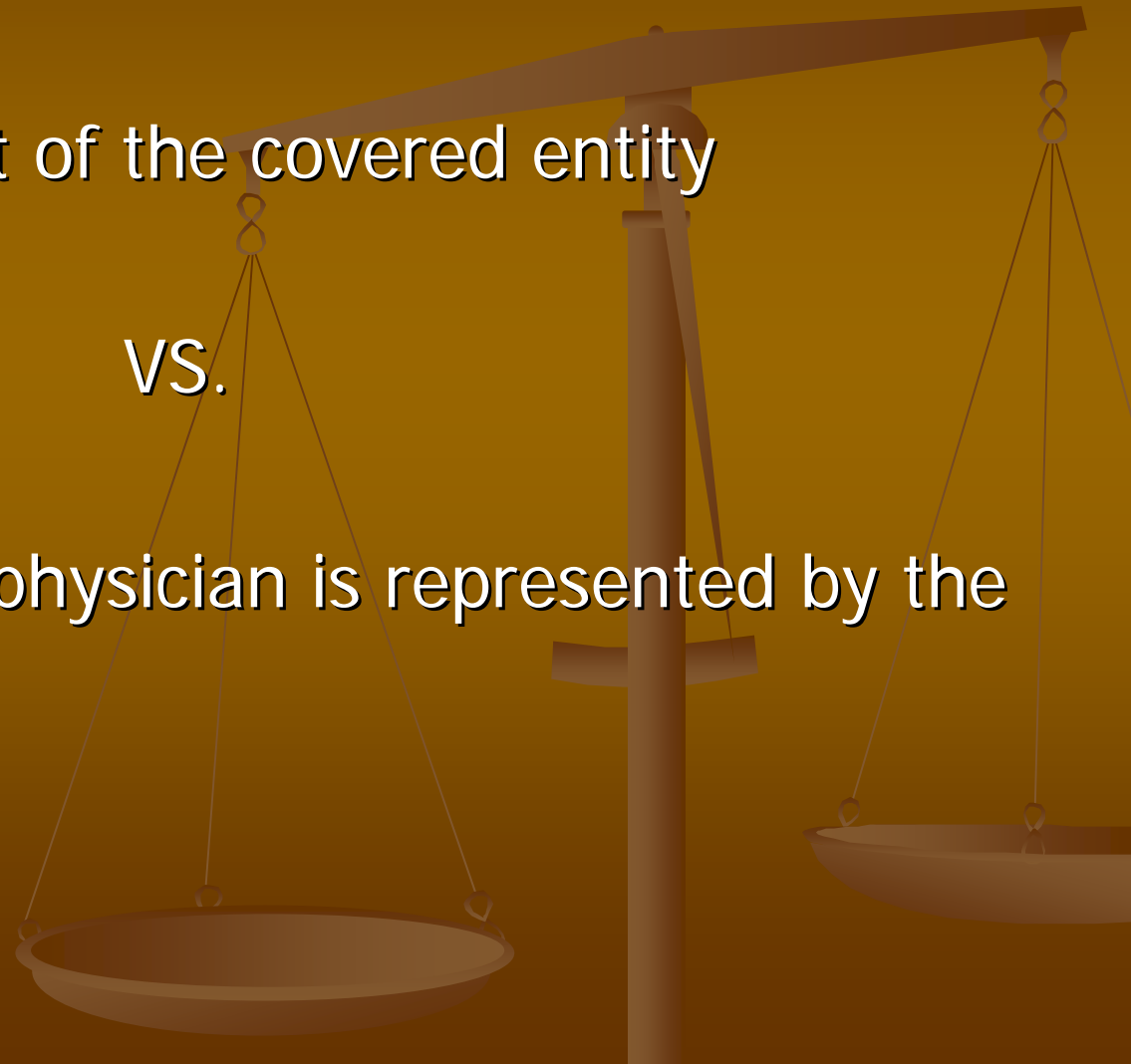
Underlying Issues

IRB Philosophies

- ❖ All faculty are part of the covered entity

VS.

- ❖ Only the treating physician is represented by the covered entity



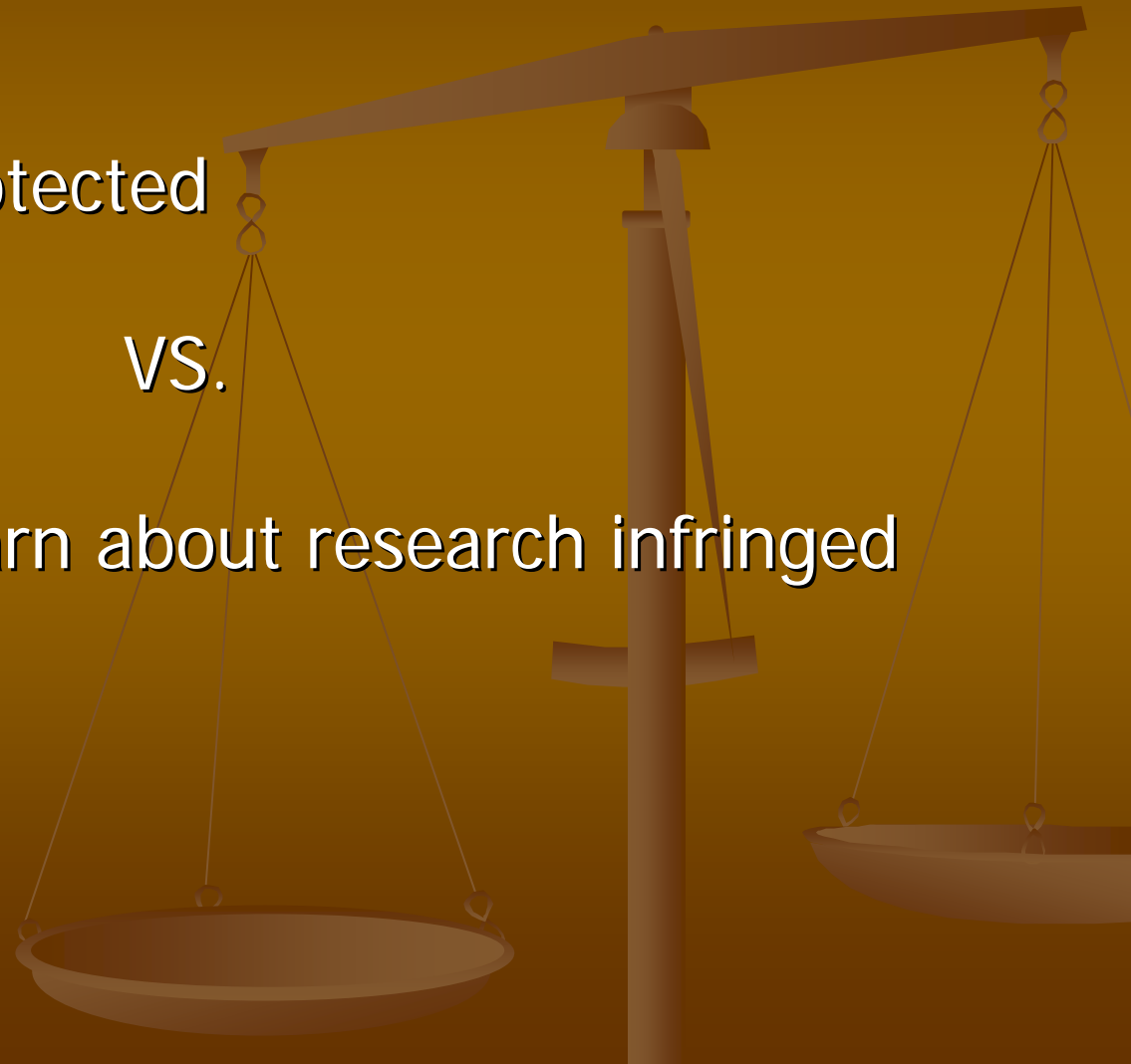
Underlying Issues

Subjects

❖ Confidentiality protected

VS.

❖ Opportunity to learn about research infringed



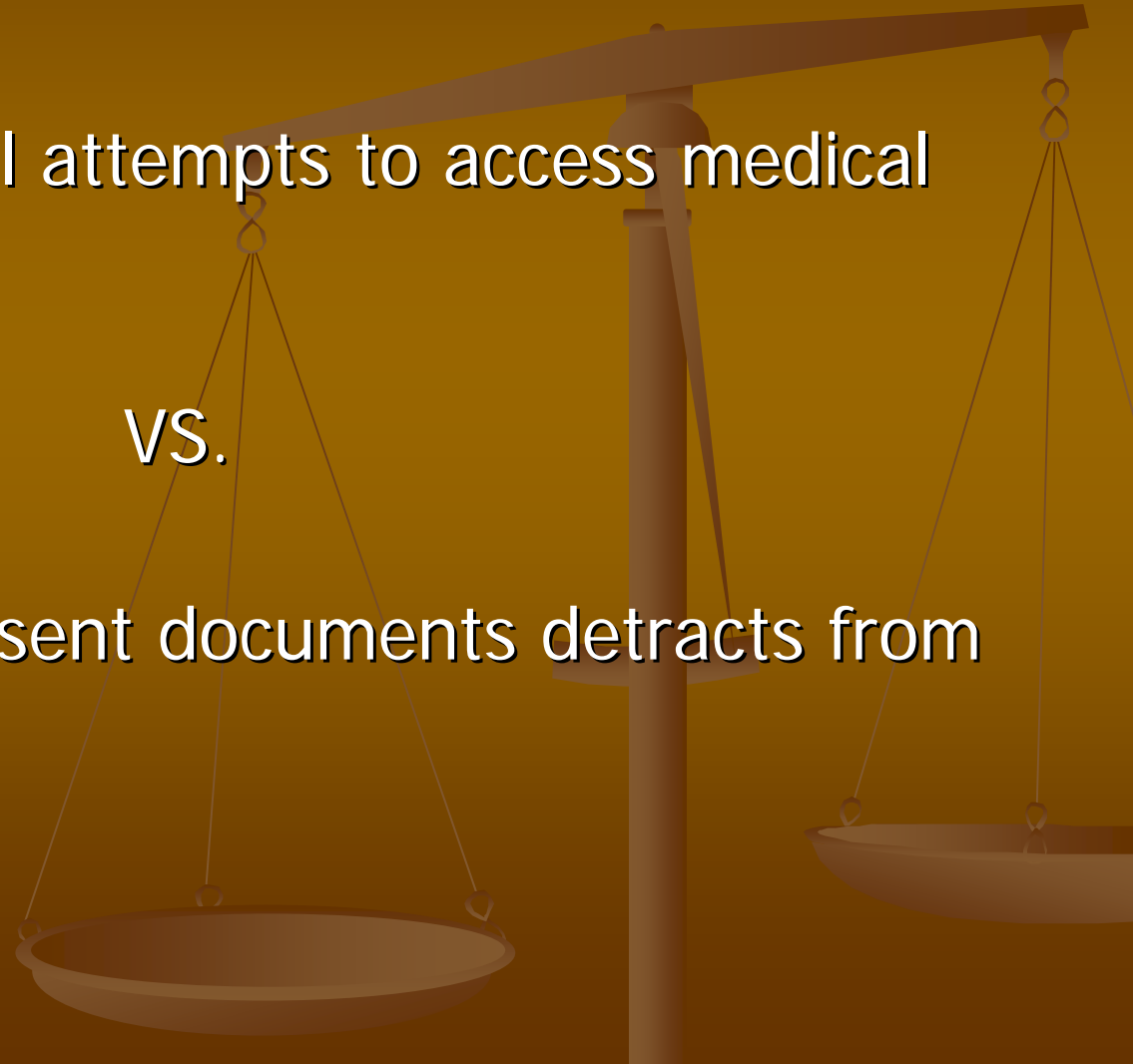
Underlying Issues

Subjects

- ❖ Informed about all attempts to access medical record

VS.

- ❖ Complexity of consent documents detracts from full understanding



Underlying Issues

Science

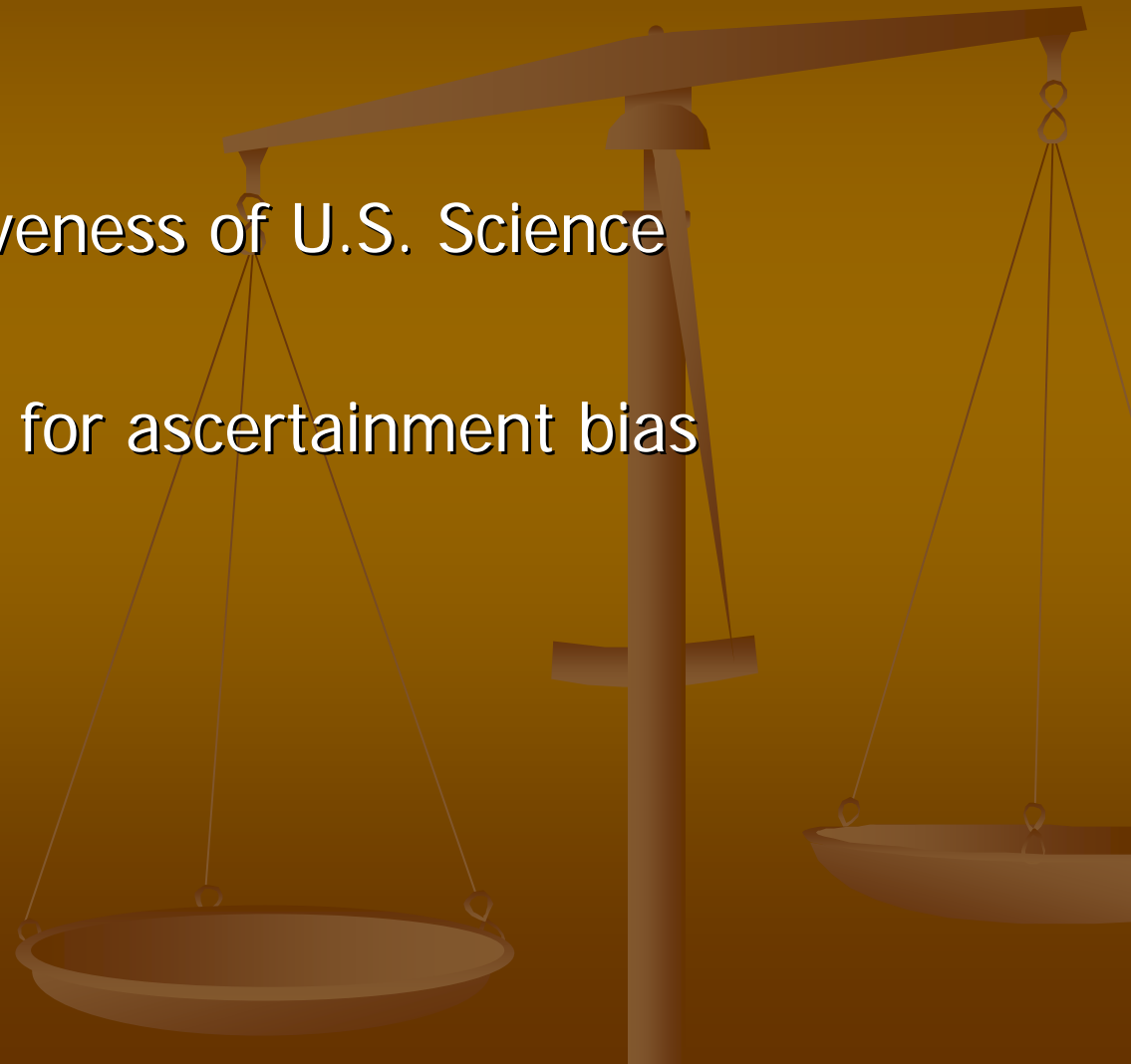
- ❖ Limits several important types of research:
 - ❖ chart reviews
 - ❖ retrospective cohort studies
 - ❖ population based C-C studies
 - ❖ multicenter studies



Underlying Issues

Science

- ❖ Hampers competitiveness of U.S. Science
- ❖ Heightens potential for ascertainment bias



What Can Be Done?

- ❖ AAMC – collection of stories
- ❖ NCVHS – ongoing review of impact
- ❖ ACE – grass roots advocacy



More Must Be Done

- ❖ Happy ending at University of Pittsburgh?
- ❖ Story must capture the imagination of the public

