



IRB Quiz

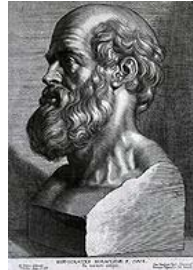
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Research Compliance Office
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Rules

- This game is multiple choice
- Can use **any resource** in the room
- Can answer the question before all the choices have appeared



The Belmont Report



What was it written to address?

NIH
Regulations

The Common
Rule

Basic Ethical
Considerations

What are the 3 principles?

- a. Democracy, Judiciary Respect and Truth
- b. Respect for Persons, Justice and Beneficence
- c. Truth, Justice and the American Way

The Belmont Report



Respect for
Persons

Is the “Respect for
Persons” principle mainly
applied through:

- a. Informed Consent
- b. Risk/benefit analysis
- c. Fair Selection of Subjects

*Remember, creation of knowledge is good, but an optional good.
Respect... for human beings is good, but a necessary good.*



HIPAA

Health Insurance, Portability and Accountability Act

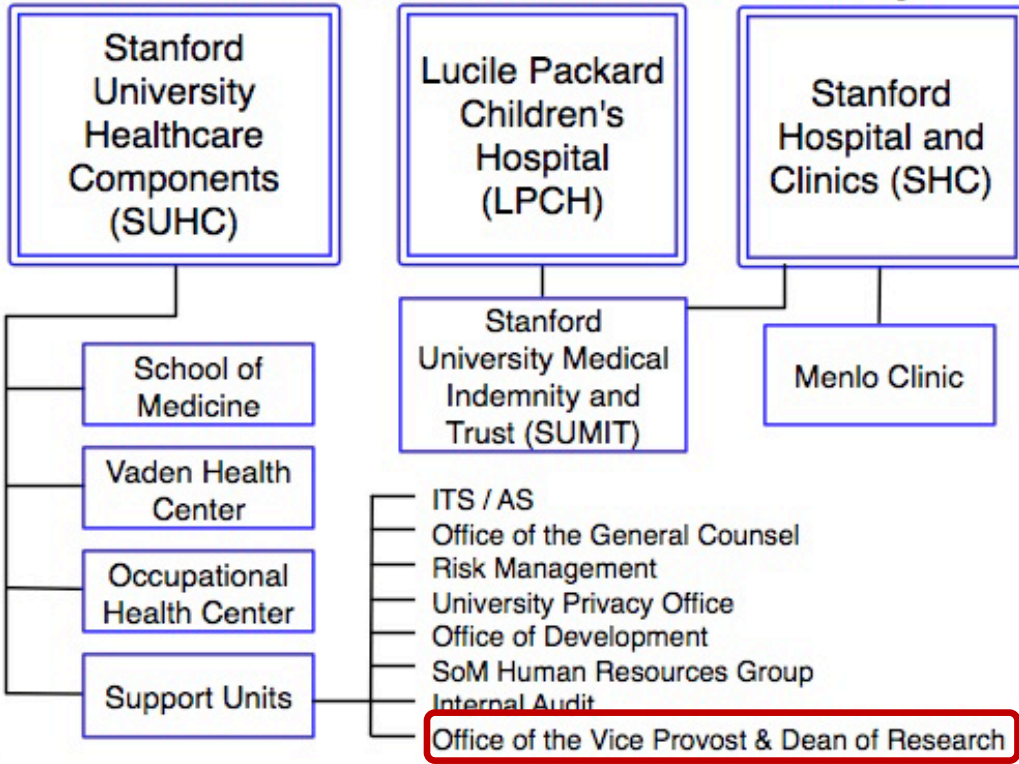
What is PHI?

- a. Personal Health Information
- b. Portable Health Insurance
- c. Protected Health Information

Who needs to take the necessary HIPAA training?

- a. Only those employed at the University
- b. All members of the workforce in the covered entity, including volunteers, service providers, and business associates
- c. RCO staff and IRB members only

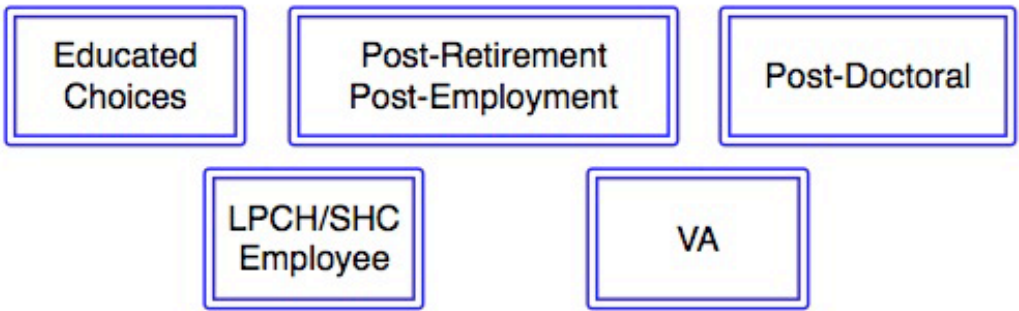
Stanford Affiliated Covered Entity



Institutional Review Board



Covered Benefits Plans



- Please remember to keep your HIPAA status current

Funding Research

In which section would you find the grant attached in the eProtocol section for a medical protocol?



Personnel Info
Participant Population
Study Location

Expedited Paragraph(s)	1-3	4	5,6	7	8(a-g)	8(h-m)	9(a-d)	9(e)	10,11	12	13	14	15	16
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What part of the grant is reviewed by the IRB?

- a. The personnel section only
- b. The budget section only
- c. The specific aims and the human subjects section

Please remember it is a federal requirement that the IRB reviews the grant to ensure it is consistent with the protocol objectives.

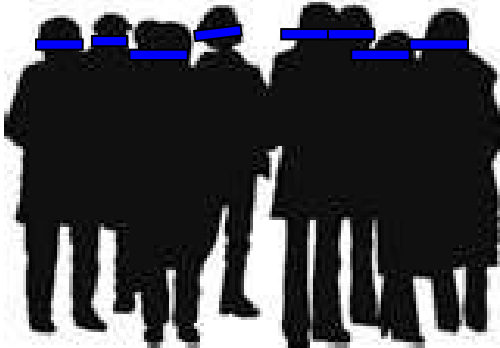
Understanding Waivers



General Requirements of IC	
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]



What type of waiver or alteration would a researcher need for research involving deception?



- Waiver of consent** – we do not want anyone to know they are participating in a deceptive study
- Waiver of documentation** – we do not want anyone to sign a deceptive consent form
- Alteration of consent** – we are altering one or more of the required elements of informed consent

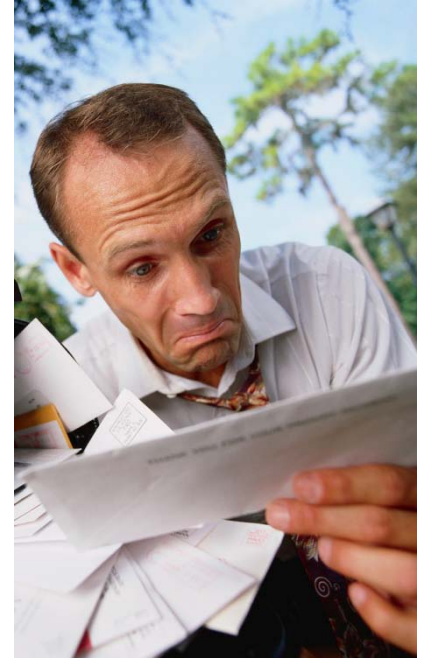
General Requirements of Informed Consent

How many required elements are there?

- a. Two
- b. Eight
- c. Fourteen

How many additional elements are there?

- a. Six
- b. Eight
- c. Fourteen





General Requirements of Informed Consent



Can you state in an informed consent:

“Stanford University requires you to waive any possibility of compensation for injuries received as a result of our negligence during your participation in research”

YES

MAYBE

NO

NO

**Cannot use language that waives or appears to waive
the rights of the subject**

Criteria for Approval



Which population does the IRB consider vulnerable?



A. Children participating in research

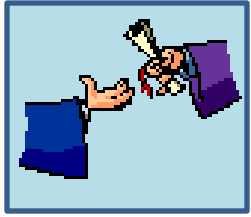


B. Handicapped or disabled persons



C. Anyone the IRB feels is vulnerable because of their circumstances

D. All of the above



As a reward for your efforts, you will receive:

- a. Free access to our website 24 hours a day, 7 days a week
- b. Your own personal training specialist who is available to answer additional questions
- c. A cupcake

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Human Subjects Website at

www.humansubjects.stanford.edu

