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
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
Please remember to keep your HIPAA status current.

Institutional Review Board

Where do we fit?

Stanford Affiliated Covered Entity

- Stanford University Healthcare Components (SUHC)
- Lucile Packard Children’s Hospital (LPCH)
- Stanford Hospital and Clinics (SHC)
- Stanford University Medical Indemnity and Trust (SUMIT)
- Internal Audit
- Office of the Vice Provost & Dean of Research

Covered Benefits Plans

- Educated Choices
- Post-Retirement Post-Employment
- Post-Doctoral
- LPCH/SHC Employee
- VA
Funding Research

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

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

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

a. **Waiver of consent** – we do not want anyone to know they are participating in a deceptive study

b. **Waiver of documentation** – we do not want anyone to sign a deceptive consent form

c. **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

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

NO
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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