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Research Compliance Office
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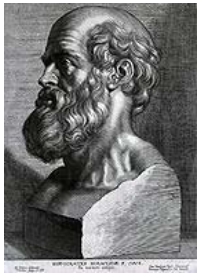
Rules

- This game is multiple choice
- Can use **any resource** in the room
- Raise hand to answer questions
- 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, including volunteers, service providers, and business associates
c. RCO staff and IRB members only

Stanford Affiliated Covered Entity

- Stanford University Healthcare Components (SUHC)
  - School of Medicine
  - Vaden Health Center
  - Occupational Health Center
  - Support Units
    - ITS / AS
    - Office of the General Counsel
    - Risk Management
    - University Privacy Office
    - Office of Development
    - SoM Human Resources Group
    - Internal Audit
    - Office of the Vice Provost & Dean of Research
- Lucile Packard Children's Hospital (LPCH)
  - Stanford University Medical Indemnity and Trust (SUMIT)
- Stanford Hospital and Clinics (SHC)
  - Menlo Clinic

Where do we fit?

Institutional Review Board

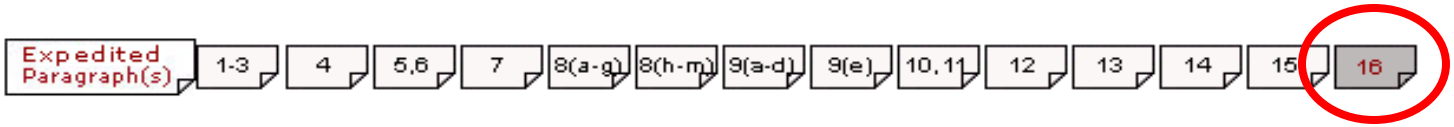
Covered Benefits Plans

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

- 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?

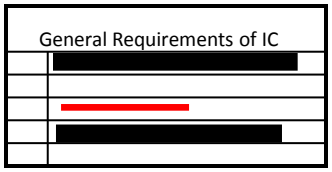


What part of the grant is reviewed by the IRB?

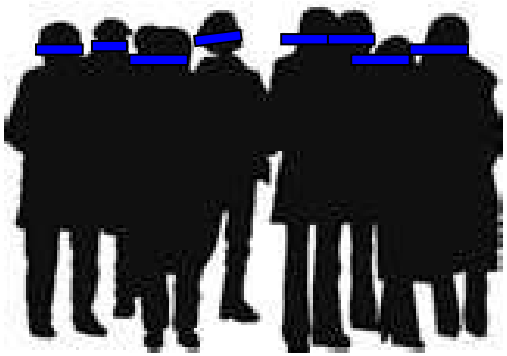
a. The personnel section only
b. The budget section only
c. The specific aims and the human subjects section

Please remember it is a federal requirement that the reviewer states the scope of the grant 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

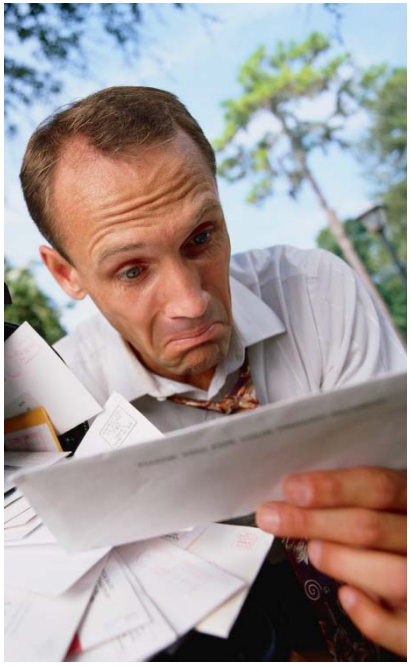
b. **Waiver of documentation** – we do not want anyone to sign a deceptive consent form

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 participation in research"

YES **MAYBE** **NO**

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

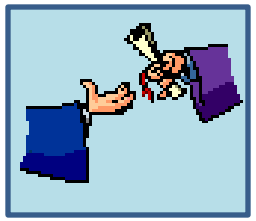
Criteria for Approval

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



Good Job! For more info…

Human Subjects Website

www.humansubjects.stanford.edu

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