

Determination of Human Subject Research and Exempt Review

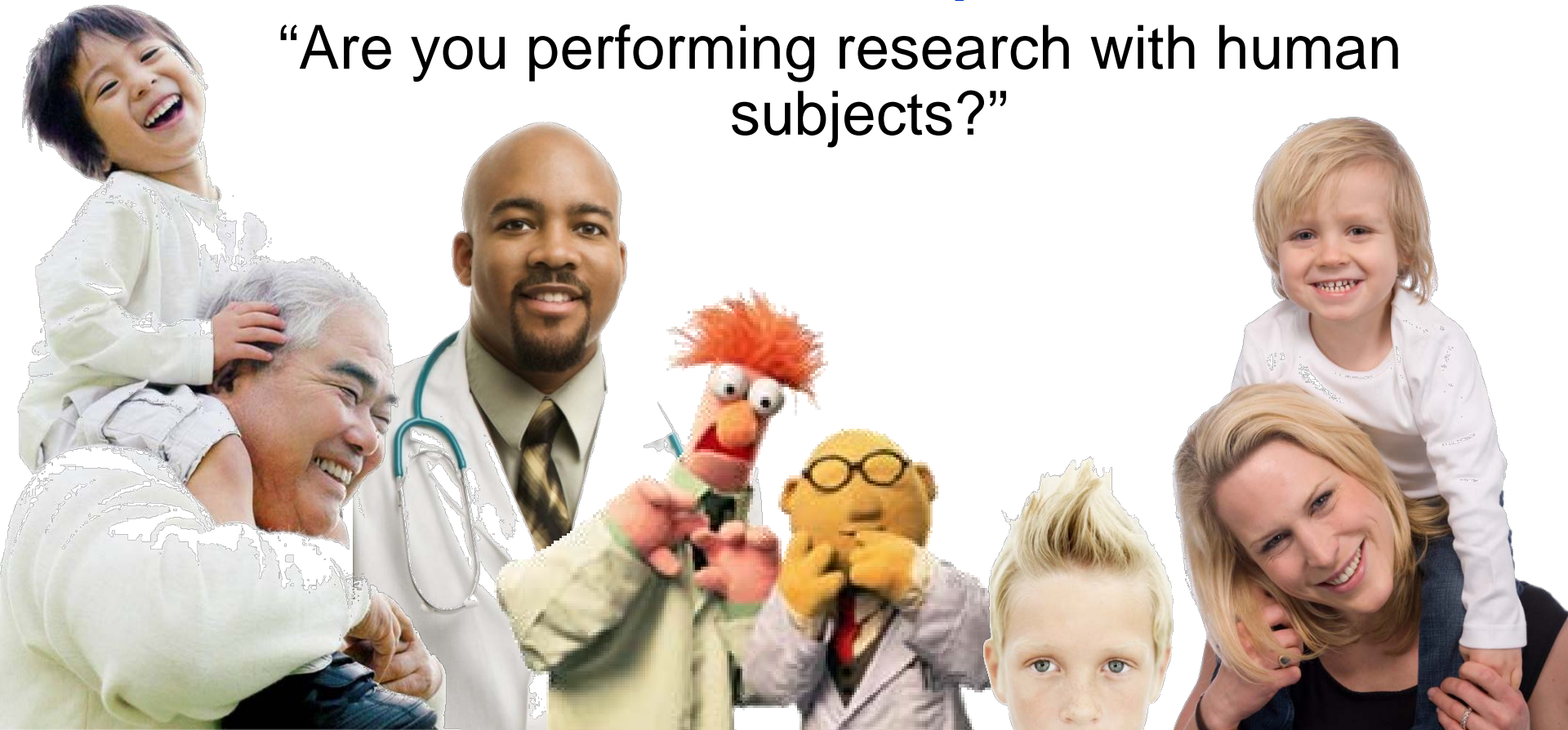
Bertha deLanda
Research Compliance Office
May 2010



Federal Regulations

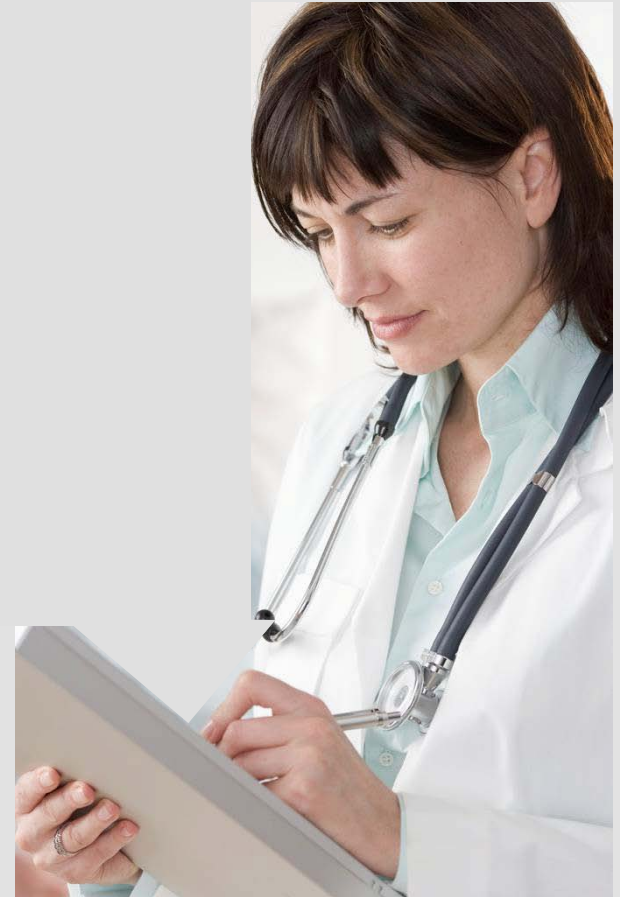
OHRP asks the question:

“Are you performing research with human subjects?”



Step by step questions:

- (1) Does the activity involve *research*?
- (2) Does the research activity involve *human subjects*?
- (3) Does the human subjects research qualify for an *exemption*?



1) Does it involve research?

OHRP Definition of Research:

A **systematic investigation** designed to develop or contribute to **generalizable** knowledge

45 CFR 46.102 (d)



- **Systematic Investigation:** Research development, testing and evaluation, i.e., the gathering and analysis of information
- **Generalizable:** Intent to draw conclusions from the research which will develop or contribute to a general body of knowledge

(2) Does the project involve human subjects?

- **Human subject** means a living individual about whom an investigator obtains data or specimens:

through **intervention or interaction** *with*
the individual *or*
their identifiable **private information**



(2) Does the project involve human subjects?

about whom

Must be **about** the person,
as opposed to just **from** a person

If you ask a person about the temperature in a room, it's FROM a person.
If you take their temperature, it is ABOUT a person.



Must be about a
WHO
And not a **WHAT**



Stanford Procedures – Human Subjects Determination Form

- Prior to submission, the researcher can submit this form **to determine if it is necessary** to go through the eProtocol application process
www.humansubjects.stanford
- If it is determined to be HSR, an application is submitted and goes through the IRB **review process**



IRB Review Process

Different Classifications of Review

- **Exempt** – human research not requiring further review (continuing review) – 6 categories

Educational Survey



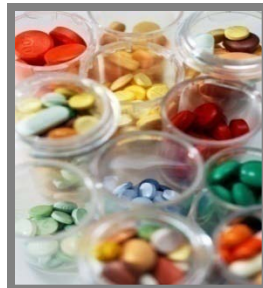
- **Expedited** – HR that falls into one or more of 9 categories – can't be greater than minimal risk

Chart Review Study



- **Regular** – involves greater than minimal risk; presented at convened panel meetings

Drug Study



Exempt

1 --- 4 ---
2 --- 5 ---
3 --- 6 ---

Different Classifications of Review

- *Normally* reviewed by members of staff
- Exempt *VA studies* - now require member review
- *Updated laminate* now included in green folders

**3) Does the research
qualify for exemption?**

Exempt	
1---	4---
2---	5---
3---	6---

Exempt Categories – 6

1. Studies conducted in educational settings



- (i) Research on regular or special education strategies
- (ii) effectiveness/comparison of different instructional techniques

Exempt Categories, cont.

2. Research involving:

- educational tests
- surveys/interview procedures
- observations of public behavior

UNLESS



- (i) Info is recorded in a way that human subjects *can be* identified *and*
- (ii) Disclosure of responses puts subjects *at risk* (e.g., civil or criminal liability)

- **Cannot** include children *except for* research involving observations of public behavior when the investigator is not an active participant

Exempt Categories, cont.

3

Research involving educational tests, surveys/interview procedures, observations of public behavior if:

- (i) subjects are elected or appointed public officials/candidates, or
- (ii) federal statute requires that confidentiality is maintained permanently

Exempt Categories, cont.



4

Involves collection\study of existing data, documents, specimens where sources:

- Are either publically available or**
- Recorded so that subject(s) cannot be identified**

5

Research\demo. projects conducted or approved by dept. or agency that studies, evaluates, or examines public benefits/service programs

Exempt Categories, cont.

Taste and food quality evaluations if:

6

- Has no additives, or
- FDA, EPA or USDA finds levels/ingredients to be safe



Examples of research that cannot be classified as exempt:...



Research that involves prisoners



FDA-regulated studies



Involves significant physical invasion or intrusion on the subject's privacy