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](http://www.humansubjects.stanford)

- If it is determined to be HSR, an application is submitted and goes through the IRB review process.
Different Classifications of Review

- **Exempt** – human research not requiring further review (continuing review) – 6 categories
  - Educational Survey
- **Regulated** – involves greater than minimal risk; presented at convened panel meetings
  - Drug Study
- **Expedited** – HR that falls into one or more of 9 categories – can’t be greater than minimal risk
  - Chart Review 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
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
Involves collection\study of existing data, documents, specimens where sources:
- Are either publically available or
- Recorded so that subject(s) cannot be identified

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:

- 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