



Research Compliance Office

Laboratory Employees and Students As Research Subjects

Bertha deLanda
Training Specialist, RCO
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Laboratory Employees/Students As Research Subjects

“In academic settings students play an integral role as subjects in institutional research”

- ❑ Perspective
- ❑ Involvement
- ❑ Eagerness to learn
- Easily motivated
- Convenient
- Easy to entice financially



Unique relationship between the participant and the protocol director (employer, instructor)



Common Rule

Additional provisions are afforded to the following populations under the Common Rule;

- **Subpart B – Pregnant women/fetuses/neonates**
- **Subpart C – Prisoners**
- **Subpart D – Children**

- **Lab employees and students are **not specifically mentioned as** requiring additional protections under Federal Law**
- **Stanford considers them a **special population****



Laboratory Employees as Research Subjects

Research Policy Handbook 7.5:

“**By virtue of their dependent positions**, employees or laboratory personnel (and students) represent a vulnerable population”

- ❑ Subjects render the **same written consent**
- ❑ Avoid even subtle **coercion**
- ❑ Studies involving **ANY type of intervention** should be considered research
- ❑ Compensation is allowed and should go to all subjects, but compensation for full-time and exempt academic staff may not be allowed



Chapter 14 HRPP Manual

Employees and Stanford University Students

“While employees and students are not vulnerable subpopulations per se, they may perceive that they are under some pressure from their superior to agree to participate. PDs must provide a rationale for involvement of employees or students of Stanford University.”



Chapter 14 HRPP, cont.

“When students (and employees) are involved, the PD must explain:

- How** they will be protected from coercion and undue influence, and
- What** alternatives to participation exist”

(HRPP 14.4)

Refers back to RPH 7.5



eProtocol Application

The researcher is required, when submitting the eProtocol application, to:

- identify who their population is (participant population),
- how they will be recruited, and
- justify the inclusion of the targeted persons



eProtocol Application

When the IRB reviews research, they:



- ❑ Determine if laboratory employees or students are included in the study



- ❑ Designed to ensure that one or more individuals is knowledgeable about this specific population



- ❑ Make sure study imposes fair and equitable benefits and burdens

(Chapters 6.4, 6.8, 9.3 and 10.1 of HRPP)

Laboratory Employees and Students as Research Subjects

RECRUITMENT

Coercion

and undue influence

Consent

on-going; age appropriate

Confidentiality

and privacy; not necessarily anonymity

Completeness

Risks/benefits

Summation

- Laboratory employees/students are considered **a special** population at Stanford
- **Recruitment/coercion** are main concerns
- Stanford accounts for this in **RPH 7.5** and **HRPP** manual
- Application of these guidelines is the responsibility of the **protocol director and the IRB**