**Office of Human Research Ethics Training Tips**

**Vulnerability, February 2017**

**Vulnerablility: Guidance from The Belmont Report**

***Adjective***

1. capable of or susceptible to being wounded or hurt, as by a weapon: *a vulnerable part of the body.*

2. open to moral attack, criticism, temptation, etc.: *an argument vulnerable to refutation; He is vulnerable to bribery.*

3. (of a place) open to assault; difficult to defend: *a vulnerable bridge.*

4. capable of being physically or emotionally wounded or hurt

5. open to temptation, persuasion, censure, etc

6. liable or exposed to disease, disaster, etc

*Dictionary.com*

**Belmont Report**

* Respect for persons:
  + Individual autonomy
  + Protection of individuals with reduced autonomy
* Beneficence:
  + Maximize benefits & minimize harms
* Justice:
  + Equitable distribution of research costs & benefits

**Minimal Risk:**

“A risk is minimal where the probability & magnitude or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” *Institutional Review Board Guidebook, 1993*

**Minimal Risk: Prisoners**

“Risk of physical or psychological harm that is no greater in probability & severity than that ordinarily encountered in the daily lives, or in the routine medical, dental or psychological examinations ***of healthy persons***...”

*Institutional Review Board Guidebook, 1993*

**The Belmont Report:**

“Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished, with as much clarity as possible. The method of ascertaining risks should be explicit… It should be determined whether an investigator’s estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.”

**Beneficence:**

* Respect for their decisions
* Protection from harm
* In Belmont beneficence is an *obligation,* not just an act of kindness. Thus,
  + *Do not harm, “secure their well-being”*
  + *Maximize benefits & minimize potential harm*

**Justice: as seen in subject selection**

* “To each person an equal share,
* To each according to individual need,
* To each person according to individual effort,
* To each person according to societal contribution ,
* To each person according to merit.”

***“Ethics & Regulation of Clinical Research”,***Robert J. Levine, Second Edition, 1986

* Comparative Justice: weighs the claims of one person against those of another.
* Non-Comparative Justice: looks at what one person is due without comparing them to others.
  + ***Distributive Justice***
    - Distribution of scarce benefits, when there is competition for these benefits.

OR

* If no scarcity, then distribution of burdens when “impose burdens on fewer than all members of a seemingly similar class of persons.”
* ***Therefore a fair sharing of the burdens & benefits that benefits all of society.***
* Belmont’s Justice
* Blend of Judeo-Christian tradition of protection of widows and orphans
* Marxist dictum “from each according to ability; to each according to need”

**Questions to ask when reviewing a proposal**

1. What risks do subjects enrolled in this study face? How can they be minimized or eliminated?
2. What are potential elements of the research design, setting, subject condition that could place the subject in a vulnerable position?
3. Is the vulnerability permanent or temporary?
4. What safeguards are in place to deal with the vulnerability posed by this proposed study?
5. Who is most vulnerable in the potential subject population to be recruited for this study?

**Beyond those groups identified in the subparts, who can you think of would be vulnerable:**

1. In what situations would those with an advanced degree never be vulnerable?
2. Are their risks for a study looking at only a group of professionals?
3. Would the size of the study cohort increase vulnerability? What about geography?