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Educating Students about Participating in Research



What's so special about students?

- High Volume
- High Risk
- Problem Prone
- Regulatory Guidance
- AAHRPP and “what works”
- Examples and Discussion



Who are students?

College students

- Students as children (age of majority)
- Students with undocumented status
- Students with other “vulnerable” identities (mental illness, addiction, impaired decision making)
- Students as pregnant women



High Volume

- Number of studies:
 - 68 % of social/behavioral research conducted with students as participants
 - Some sites also have high volume of student investigators conducting research with student participants

AAHRPP Elements: Rethinking in terms of Students

- I.1.A What is research?
 - Description of “students” and “student research”
- II.1.A. IRB representation
 - If research frequently involves students, do students serve on IRB? Are their needs represented by specific IRB members?



High Risk: Students as vulnerable participants

- **Informed Consent**
 - Age of majority
 - Voluntariness
 - Coercion and undue influence
- **Confidentiality and Privacy**

Voluntariness

- Complete voluntariness: no penalties, no grades, no alternatives (non-curricular)
- Alternatives (curricular)
 - Extra credit only
 - Extra credit with options
 - Extra credit without options
- Alternatives (curricular)
 - Papers, coursework (seen as negative!)
 - Penalties imposed



Voluntariness?

- Illusion of choice does not eliminate undue influence
- If voluntary (non-curricular) then alternatives should also be non-curricular



Example 1: Student Research Pools

- Discussion points:
 - Voluntariness
 - Compensation
 - Withdrawals
 - Informed Consent

Pools

- Penalties, Options
 - “All ____ students are expected to participate in research studies.”
 - “If you prefer not to take advantage of this learning opportunity....”
 - “Most of what you learn in ____ is based on research studies like this one...”

AAHRPP Elements: Rethinking in terms of students

- II.3.F. Consent
- II.4.A. Protection of individuals who are vulnerable to coercion or undue influence
 - What information does the HRPP make available to researchers and participants with respect to students?



Confidentiality and Privacy

- How are students asked to participate?
- How is classroom participation (required) based on what is revealed in research process (consent through completion)?
- How is information (data) collected, stored, accessed?
- Electronic sign up (no personal recruitment)

Example 2

- Example from course syllabus:
 - “Participation in research is essential to learning. If you choose not to participate, you may be asked to complete alternative assignments. Please see the instructor during office hours to discuss any concerns about this policy.”



Example 2: Special protections

- Discussion points:
 - Vulnerable to undue influence, coercion
 - Alternatives to participation
 - Consequences (real or perceived)

AAHRPP Elements

- II.3.D. Privacy
 - How and when consent is given
 - “Seeing” and “being seen”
- II.3.E Confidentiality
 - Information “revealed” in research finds its way into classroom lecture/discussion
 - Age of majority and “legally authorized representatives”



Problem Prone

- Equitable selection
- Risks and Benefits
- Conflict of Interest



Equitable Selection

- Why students?
 - Equitable selection: does this population have special needs or do they represent a special group?



AAHRPP Elements

- I.1.F. Scholarly/scientific validity
 - Why are these participants appropriate?

- II.3.C. Equitable Selection of participants

AAHRPP Elements

- II.3.A. Risk/benefit analysis
 - What are the **direct** benefits?
 - Often “educational benefits” are not evident, not assessed
 - Are the benefits at least as favorable as that presented by the alternatives?



Problem Prone

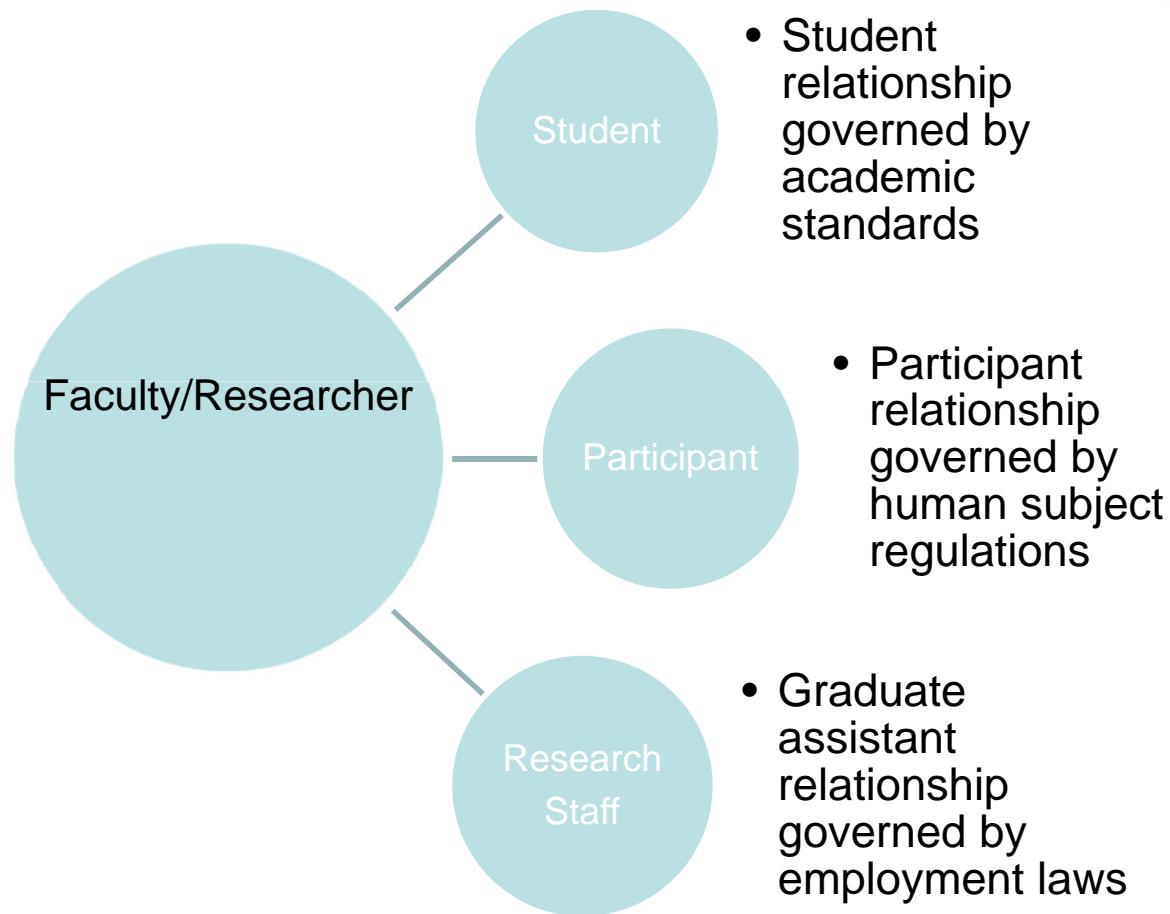
- Dual roles:
 - Teacher/Researcher
 - Student/Participant
 - Student/Research Staff
 - Teacher/Supervisor
- Dual loyalties: institution, profession
- Dual obligations: integrity of research; protection of participants



Problem prone

- Those potentially troublesome issues:
Example: High dominance, low concern in voice tone are associated with higher malpractice suits in surgeons. How do students **perceive** a “request” to participate in research from their professor?

Multiple roles





Conflicts of Interest

- Institutional Conflicts
 - Vested interest in research, outcomes
 - Responsibility to students
- Investigator financial conflicts
 - Same or different?



Example 3

- “Managing” conflict of interest
- Psychology students, interns, student records, student research, and sponsored projects: what’s an IRB to do?



Rethinking the Elements

- II.2.A. Conflict of interest and review
 - Do policies account for student-related conflicts?(Decisions on scholarships, internships, funded graduate/research assistantships)

Regulatory Guidance: A “management” approach

- OHRP
 - January 8, 2010: Imposing penalty credits for student participant pools when students fail to show up violates regulations
- FDA, PHS, NSF
- FERPA
 - Creates no privately enforceable rights, but protects disclosure of records



Regulations, continued

- PPRA- regulates disclosure of information obtained directly from students through surveys, evaluations, or analysis



Rethinking the Elements...continued

- I.4.A Problem resolution process
 - How does the student appeals process work in relationship to the IRB process of managing complaints and reports of problems?



Rethinking the elements...

- I.4.C. Involvement of “community”
 - Do students take part in policies, research design?
 - How are our outreach efforts directed toward students



AAHRPP Elements

- I.1.E. Education and Training
 - Is any of it directed at students?



AAHRPP Elements

- III.1.A, II.1.C., II.1.D., III.1.E., III.1.G.:
Researchers and research staff have protection of rights and welfare of **participants** (students) as **primary** concern



What works? Key elements for managing risk in student research

- No penalty for no show
- Debriefing and resources available to students
- Credit given for arriving on time at research site
- Menu of alternatives/non curricular
- Active and passive consent: the difference between opting in and not opting out



4 C's for Careful attention

- Consent
- Confidentiality
- Coercion/undue influence
- Conflict of interest



Summary Points: IRB determinations

- Risk and burden: what is the direct benefit to students?
- Voluntary participation (freely given, does not result in penalty, indirect recruitment)
- Confidentiality and Privacy (student access to participant information and consent process)
- Use of class time
- Additional safeguards: age, right to withdraw, sign-in separated from consent



Students are like that....

- Doing you a favor—*quid pro quo*
- Doing something that will help you remember me
- Doing what you want me to do
- Figuring out the rules of the game: “Hidden Curriculum”



Point to ponder...

- In the “research culture” of our organizations, what are students as participants “catching” about their role as participants? As future researchers?