OHRP Research Community Forum 2013
"Planning for the Unexpected: Employees As Research Participants"

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Barbara Higgins
Research Education and Process Improvement

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Regulations and Guidance

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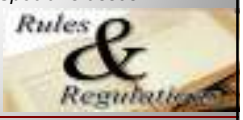
- No explicit protections for employees as research subjects
- Investigators implement additional safeguards to protect welfare vulnerable participants
- 45 CFR 46 supplemental regulations for some vulnerable populations, including children, prisoners and pregnant women
- OHRP IRB Handbook: Chapter VI, *Special Classes*
  -includes employees with other vulnerable pops as "special classes"



Regulations and Guidance

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- "An investigator shall seek such consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of **coercion** or **undue influence**."45 CFR 46.116
- Are coercion and undue influence concerns for employees who serve as research participants?

Scenarios

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Scenario 1:

- A research employee, Ted, contacted via email by Dr. Smith
- No reporting relationship, joint work
- Minimal risk, blood/sputum samples, healthy volunteers
- Few more participants, enough data for grant
- Consent process lacking
- Ted presumed to be knowledgeable
- Ted realizes he has provided workmates access to his medical records for next 5+ years

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Scenarios

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Scenario 2:

- Research lab staff providing samples for research purposes without consent
- "testing method"; Normal, expected practice in labs everywhere, considered being part of scientific community

Scenario 3:

- A research nurse asked to consent and provide samples for three minimal risk studies during her first week on the job
- "Everyone working here is enrolled in these studies"

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Scenarios

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Scenario 4:

- Routine QA audit of consent noted:
  - participant a new employee/trainee
  - consent provider direct supervisor/preceptor
  - witness another manager within department
  - PI not involved in consent process but department chief and physician staff work with most
  - Most of department staff were participants, similar consent procedures

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Scenarios

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- Tragic death Ellen Roche at John Hopkins in 2001
- 23 year old healthy volunteer in asthma study
- Inhaling chemical to monitor lung response
- ARDS and died
- Investigative committee identified institutional issues, such as IRB, PI, protocol deficiencies, which have been addressed
- "Institutional culture made tragic outcome more likely", "culture of possible coercion"

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Scenarios

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- Employee, lab technician at the Asthma Center
- Received $365 and time off during the workday
- Most study participants were employees
- Ellen participated in many previous asthma center studies

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Coercion and Undue Influence

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- Are **coercion** and **undue influence** concerns when employees serve as research participants? Let's discuss these terms

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Coercion

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- An overt or implicit threat of harm intentionally presented by one person to another in order to obtain compliance. *DDHS*
- Example: consent provider implies refusing to enroll will lead to a poor performance evaluation
- Coercion may be more subtle
- Employee may enroll in study due to fear of retribution when workplace culture encourages staff to participate

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Coercion

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- Those who decline seen as outsiders, uncooperative, not part of scientific community, not committed to departmental success
- Employee-employer relationship = power imbalance; can create employee perception coercion, even if researchers well intentioned

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Undue Influence

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- an offer of an excessive or inappropriate reward or other overture in order to obtain compliance.
- Example: offering extra time away from work to join a research study, preferred work schedules or better work assignments
- Employees may enroll to gain favor and please supervisors, admin. or and physicians
- Hope in return for enrolling, job perks

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Voluntariness

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- Central tenet research ethics is potential participants *must feel free to decline!*
- Employees dependent on employers
- Power imbalance may interfere with employee's capacity to act freely

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Confidentiality

- Employees may be at greater risk for loss of privacy and confidentiality when research involves collecting PHI or other sensitive information
- When workplace and research setting also the health system where the employee receives medical care, risk heightened

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Policy

- Aim: avoid coercion and undue influence while promoting voluntariness and confidentiality for employee-participants

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Policy

- Beaumont employees are vulnerable.
  -additional safeguards when they are included in research
  -IRB submission indicates if employees included
  -recruitment activities, incentives/compensation reviewed
- Under no circumstances may researchers coerce or unduly influence an employee to participate
- Researchers must ensure employees understand participation is not required and refusal will not affect employment

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Policy

- An employee may not be required to participate in research as a condition of employment
- Employees may not be directly solicited (by phone, email or in person) by a member of their current department, a peer, an administrator, or medical director
- IRB-approved posters preferred recruitment means

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Policy

- Studies both non-therapeutic and > minimal risk: employees who report directly to PI (or whose supervisor reports directly to the PI) **may not** participate
- Researchers and staff may not consent individuals who report directly to them. If an employee requests information, researchers can provide objectively, 3rd party must conduct informed consent
- Recruitment and research activities should not be conducted with supervisor or peers present. Supervisors and peers should not be informed about whether or not an employee joins a study

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Policy

- When supervisors or administrators are part of research team, they should review aggregate data stripped of identifiers
- Participant's status as an employee and special precautions must be documented in the consent process note.

-inquire relationships with research team, emphasize voluntary nature of participation, no effect on employment

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Not Included in Policy

- Do not prohibit employee participation in Beaumont research

-interfere with personal autonomy and deny employees potential benefit

-fairness of risk distribution and impact public's trust

- Do not require investigators to keep a list of employee-participants

-CDC requirement-supplied to IRB to facilitate interviews of participants for investigations of alleged coercion

-privacy and confidentiality concern

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Questions

Thank you for your attention!

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