Engaging the Community of Workers, as Research Participants and as Partner-Advocates in Safeguarding their Rights and Ensuring Scientific Integrity in Workplace Research

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Foundations of Trust: Connecting Our Community to Research
Hartford, CT

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I do not have any actual or potential conflicts of interest in relation to this program to disclose.
About NIOSH

Mission: To develop new knowledge in the field of occupational safety and health and to transfer that knowledge into practice.

Vision: Safer, healthier workers

Values: Relevance, Quality, Partnership, Transparency, Impact, Diversity
Agenda

• The Evolving Nature of the Workplace
• Vulnerability in Human Subjects Research
• Ethical Duties to Vulnerable Subjects
• Vulnerability and Occupational Safety and Health Research
• Safeguards to Protect Workers
• Engaging Workers as Partner-Advocates
The Evolving Nature of the Workplace

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The Evolving Nature of the Workplace cont’d (1)
Vulnerability in Human Subjects Research

The Concept

• No generally accepted definition
• “Grandfathered into the lexicon, lore and literature of research ethics without undergoing stringent certification.” (Kipnis, 2001)
• Groups often identified as vulnerable in ethical guidance
Vulnerability

Federal Policy

45 CFR §46.111 Criteria for IRB approval of research

(a)(3) Selection of subjects is equitable. In making this assessment the IRB [...] should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
Vulnerability

2002 CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects

“'Vulnerability' refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group.”
Vulnerability

Conceptual limitations

• Individual and situation-specific
• Concerns about categorical classification
  • Over-broad
  • Pejorative label
  • Unwarranted paternalism
Vulnerability

Evolving Conceptions

• Proposed Revision to the Common Rule: Vulnerable to coercion or undue influence

• The Moral Marker Approach: Wrigley and Dawson: “A marker that additional consideration needs to be given to whatever ethical issues there may be.” (Barrett, 2015)
Vulnerability: A Functional Definition

Vulnerable: increased possibility of harm due to one’s inability to protect one’s own interests

Risk: possibility of harm
Harm: social, economic, psychological and physical injury
Ethical Duties to Vulnerable Subjects

Respect for persons demands that researchers and IRBs establish safeguards

Beneficence demands that researchers and IRBs ensure all risks to subjects are minimized

Avoid exacerbating existing vulnerability and creating new vulnerability

Establish safeguards to protect the rights and welfare of vulnerable subjects
Vulnerability and Occupational Research

The Case of the Over-Enthusiastic Subjects
Vulnerability and Occupational Research

Possible Harms to Workers

(non-exhaustive)
Vulnerability and Occupational Research

Roadmap to identify conditions that could increase the possibility of harm to workers
Unique Characteristics of the Workplace

- Long list of stakeholders
- Subjects are generally healthy volunteers
- The presence or absence of unions
- The evolving nature of the workplace

Stakeholders:
- workers
- employers
- unions
- insurers
- government
- community
- researchers
- occupational medical professionals
- institutions

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Unique Characteristics of the Workplace

Conditions with possible impact on decisional autonomy

• Power structure
• Hierarchical relationships
• Closed community
Characteristics of Occupational Research

Conditions with possible impact on confidentiality

- Small workplaces
- Multiple studies on the same worker population
- Employer and possibly union possession of personnel records
- Published research results
- Individual test results
Characteristics of Occupational Research

NIOSH IRB Members:

“Workers are not totally free in the work setting.”

“You can’t hide participation when the study is on-site.”

“It can be hard to keep research data from prying eyes.”

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Characteristics of Occupational Research

Disaster Research with Workers – Responders, First Receivers and Disaster Workers

• Informed consent
• Physical security
• Informational security
• Psychological stress
Characteristics of Occupational Research

Occupational Epidemiologic Studies

• Assess the relationship between exposure and adverse outcomes to understand risk

• Sampling frame and types of possible interventions differ from population-based studies
Characteristics of Occupational Research

Genetics in Occupational Health Research

- Variable human response to occupational hazards
- Studies can involve biospecimens, records, interviews and questionnaires
- Interpretation of group and individual results
- Clinical relevance and the variety of preventive actions
Characteristics of Occupational Research

“The rights of workers who volunteer to participate in research, including genetic research, must be protected. This protection must minimize the potential for misinterpretation, misuse, and abuse of genetic information by addressing issues such as privacy, confidentiality, notification, and the implications of the results for workers and their families. Providing the worker with a clear explanation of these and other aspects of a study during the informed consent process is the cornerstone of this protection.”

(NIOSH, 2009)
Safeguards to Protect Workers

Rose’s Worker Study Participant Bill of Rights

(Rose & Pietri, 2002)
Safeguards to Protect Workers

Promoting Decisional Autonomy (Voluntariness)

• Stakeholder involvement in study design and implementation
• No supervisor involvement in recruitment
• No stakeholder pressure to participate
• No job impact on refusal to participate or withdrawal
• For genetic studies, investigators should inform subjects whether genetic biomarkers have clinical meaning and have been validated

(Rothstein, 2000; Rose & Pietri, 2002; NIOSH, 2009)
Safeguards to Protect Workers

Limiting Potential for Breach of Confidentiality

- Disclose to subjects all personnel who have record and result access
- Clearly indicate whether subjects’ information will be used in future studies
- Prohibit supervisor access to subject lists

(Rose & Pietri, 2002; Rothstein, 2000)
Safeguards to Protect Workers

Disaster Research with Workers

- Robust attention to physical and informational security concerns
- Establish support mechanisms
- Robust strategies and processes to obtain informed consent

(Hunt, Anderson & Boulanger, 2012; Curry, 2014)
Engaging Workers as Partner-Advocates

NIOSH Policy


Risk Communication Policy for NIOSH Epidemiologic Studies (2013)
Conclusion

Together, with the community of workers as partner-advocates, we can safeguard their rights and promote the integrity of occupational research.
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Questions?
References