

Washington Human Research Protection Office – Behavioral Minimal Risk Subcommittee (IRB)

Special Considerations when Research Participants are *Employees in the Workplace*

Overview

Social-behavioral research often examines employer-employee relationships or other research topics pertaining to employees in the workplace. IRBs consider this participant group a “vulnerable population” because their agreement to participate may not be entirely voluntary, due to the inherent imbalance of power between employer and employee. For example, employees may participate because they believe that doing so will enhance their position in the organization or from fear that failure to participate will negatively impact their employment. Although specific federal regulations do not exist for this population, the regulations are clear that IRBs should ensure that adequate safeguards are in place to protect the rights and welfare of individuals, which may be vulnerable to undue influence or coercion. This would include employees in the workplace.

Ethical Considerations

- Participation in research should be voluntary and free from coercion or undue influence.
- Data should be adequately protected to ensure confidentiality.
- In addition to obvious physical risks, research risks also include information that could place participants at risk of criminal or civil liability or be damaging to an individual’s financial standing, employability, or reputation.
- Research involving collection of data on sensitive topics presents risks to participants which they should be aware of and from which they should be protected to the greatest extent possible. The close environment of the workplace amplifies the need for this protection.
- The risks and sensitivity of the data should be considered in the context of the research. For example, identifiable surveys questioning employees’ opinions on the effectiveness of management or ethical behavior of organizational leaders poses a significant risk to the individual’s employment, and possibly reputation, if a breach in confidentiality should occur. Conversely, a completely anonymous survey of the same factors reduces that risk, and would be preferable, if the research question could be answered without identifying information.

Tips for Expedited Review

Studies that include the following safeguards to minimize risk to participants will be reviewed by the Behavioral Subcommittee. Studies that are not designed with these protections may be referred to a convened IRB (full board committee) for review.

1. **Letter of Support.** Written permission from an authorized representative of the organization (typically CEO or President) for the research to be conducted at their site. This document should include the following elements:
 - a. acknowledgement of the research procedures, including what their own and their employees’ participation will involve;
 - b. assurance that an employee’s participation or non-participation will not affect future performance evaluations or employment status;
 - c. a brief statement about whether management will be informed of who did or did not participate; and

- d. attestation of whether individually identifiable information collected in the research will be shared with them.
2. **Recruitment Process.** By way of announcing the organization's participation in the research project to employees, the CEO/President should include each of the above elements in the communication. The information may be communicated orally, such as at a staff meeting, or in writing. If the information will be provided in writing, HRPO requires a copy of the exact verbiage that employees will receive.
3. **Consent Process.** The PI/PD should repeat each of these assurances in the consent form or script provided to participants, in addition to the other standard elements of consent, as they apply to the research.
4. **Consequences of breach in confidentiality.** Potential breaches in confidentiality are an inherent risk in any research involving humans. The potential consequences of such breaches in employee-employer research; however, adds an additional burden on the part of researchers to protect participant identity and data. Plans for maintaining confidentiality, including information about (i) security for the electronic transmission and storage of data; (ii) identifiability of stored data; and (iii) plans for archiving the data should be provided in detail. Researchers should take every step possible to ensure that potential participants are aware that, although minimal, there is always a risk that their identity and/or data could be disclosed.
5. **Studies involving comparison of existing data with prospectively collected data** (e.g., attendance records or performance reviews and behavioral observation, interview, or questionnaire). In addition to each of the above elements, consent must be in writing and must include a clear description of any employee records that will be used in the research.

3/5/09

References:

- 45CFR 46.111(b) Criteria for IRB approval of research.
- AAHRPP standards (version date 1/19/06), Element II.4.C. Participants vulnerable to coercion or undue influence, including employees in the workplace.
- Office for Human Research Protections (OHRP), IRB Guidebook, Chapter VI: *Special Classes of Subjects*, Robin Levin Penslar