NEW SOLUTIONS, Vol. 15(1) 53-59, 2005

PARTICIPATORY ACTION RESEARCH: A PROTECTIVE RESEARCH DESIGN

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ABSTRACT

This commentary briefly reviews the ethical considerations for protection of workers participating in research. We argue that many IRBs may not fully understand the nature of collaborative and participatory research methods; consequently, this may delay IRB approval or worse, reduce the effectiveness of IRB oversight. A U.S. workplace participatory action research (PAR) project with which we are involved illustrates how researcher-worker-employer teams can navigate human subject oversight procedures (IRB approval). By design, successful and effective PAR projects incorporate, and often exceed the ethical principles espoused by current IRB principles.

Unfortunately, evidence of ethical breeches in occupational health research are available in the literature. For example, the asbestos industry has a long and unsavory record of violating respect for persons, beneficence, and justice by withholding medical results, knowingly exposing workers to the carcinogen, and failure to obtain informed consent [1]. More recently, an investigation into an apparently new occupational lung disease was thwarted by both industry and an academic institution when findings that would confirm the diagnosis of flock-worker's lung were blocked from publication in the peer-reviewed literature [2, 3]. In these instances of research abuse, workers were blocked from a full understanding of work exposures that affected their health, a clear breach of informed consent, right to know, and beneficence (does the research harm or benefit the individual?).

*Kate McPhaul represented Jane Lipscomb at the symposium honoring June Fisher and Fisher's career advancing worker health through participatory research. This invited article reflects conversations with June and others, about our experience obtaining human subjects approval for participatory occupational health research projects.

There are a number of referenced works about the ethics of doing research in the United States.[1] Whatever the reference, the first issue is coverage. In a major report issued in 1999, the National Bioethics Advisory Board (NBAC) issued recommendations that included the concern: "Federal protections for persons serving as subjects in research do not yet extend to all Americans" [4]. It referred to the "Common Rule," the set of federal regulations addressing the protection of human subjects in *federally-sponsored research* (45 CFR 46, Subpart A). This means that, if research projects in the United States do not receive federal funding, the sponsor is not required to follow federal guidelines to protect human subjects. Therefore, workers may participate in employer-sponsored research not subject to federal ethics oversight. Theoretically, occupational health and safety research involving unions and other worker organizations could avoid IRB oversight as well.

Occupational health researchers should make every effort to protect workers' rights by following federal guidelines for ethical treatment of human subjects, regardless of their sponsors. Participatory action and other collaborative research projects do meet the U. S. government's definition of research in the "Common Rule" and, therefore, are subject to oversight by human subjects institutional review boards (IRBs). In fact, participatory action research (PAR) involving worker and/or employer groups is well-suited for collaboration with academic investigators whose research is governed by an IRB or the establishment of an organizational level human subject's review committee according to the "Common Rule" recommendations.

WORKERS AS A VULNERABLE POPULATION

NBAC recommendations include a higher level of protection for certain vulnerable populations or populations at higher risk of exploitation. Employed people are considered a vulnerable population, especially in employer-sponsored research or research taking place at the worksite. Rothstein and others argue that workers should be given the additional protection or the higher level of consideration often reserved for children, the mentally ill, and pregnant women [5, 6]. This is because most workers cannot afford to jeopardize their jobs and income by appearing uncooperative with employer-sponsored research. Similarly, workers may not want to jeopardize their relationship with their union or with researchers in PAR projects. Therefore, extra precautions must be taken to assure that participation in occupational safety and health research is not coercive or damaging to the worker. Participatory research designs by their nature protect workers from exploitation by researchers because of worker involvement in all

[1] The "rules" may be different in other countries, although the general principles still apply.

stages of a research project, especially formulation of the research questions, development of the intervention protocol, and dissemination of the findings.

EVALUATION OF OSHA WORKPLACE VIOLENCE PREVENTION GUIDELINES

In 1999, a union representing mental health workers in a state mental health system brought their data from a pilot study about workplace violence to our university occupational health research group. Their preliminary intervention data were used to write a proposal that was funded to evaluate a large-scale intervention of a participatory process to reduce workplace violence in state mental hospitals. The proposal stage involved partnering with the health and safety departments of three unions, using the pilot data demonstrating feasibility, obtaining an employer letter of commitment to the project, forming a project advisory group, and coordination from the university occupational health research team. Procedures to protect human subjects were described in the proposal.

Once funded, the university-based researchers obtained human subjects (IRB) approval from their university, but also had to get IRB approval from each of the seven state mental health facilities participating in the project; we also had to obtain a supervisory IRB that provided oversight for the entire system. The extensive and complicated human subjects review process was required because the mentally ill are considered a vulnerable population and this state mental health system has extensive human subjects review procedures. Ultimately, nine separate IRBs reviewed this project each year for four years.

Currently, all research personnel, including data entry staff, interviewers, union partners, and all key personnel, must complete mandatory IRB training. [A consortia of more than 400 research institutions utilize an extensive web-based training program which reviews the history of human subjects protection.] A critical part of this training is review of the 1979 Belmont Report that synthesized ethical obligations of researchers to subjects in one document. It describes three principles that should carry equal weight when IRBs review research involving humans. These three important principles are respect for persons (autonomy), beneficence (does the research harm or benefit the individual?), and justice (fairness of the project) [7]. Although these principles may potentially conflict with one another, they all must be considered. We review these principles briefly in the context of our participatory violence prevention project to illustrate some concrete strategies that can help participatory researchers navigate the human subjects oversight process.

Respect for Persons

Participatory research maximizes autonomy and respect for persons because workers are recognized as full partners in the research process. The Workplace Violence Intervention Project included worker representatives as

co-investigators. Making workers key personnel formalizes these important relationships with funding agencies and the IRBs. The informed consent and information-sharing procedures afforded respect and autonomy to all participating workers. Those who participated in focus groups had to review and sign informed consent forms. The forms were waived for the two anonymous surveys, but a cover letter explained the survey and a study representative was available to answer questions.

Our university participates in the Collaborative IRB Training Initiative (CITI) training, used by more than 400 groups and universities. CITI recommends asking these questions of the project to ensure "respect for persons:"

- Does the consent process maximize autonomy?
- Does the protocol maximize autonomy?
- What additional protections are in place for vulnerable populations (i.e., workers, to avoid adverse employment consequences)?
- Does this study maximally protect subject privacy and confidentiality?

Beneficence

One role of IRBs is to evaluate the necessity and importance of the research. They are supposed to make sure that vulnerable populations do not disproportionately bear the burden of research without receiving the benefits of the findings.

Participatory projects, especially those deemed "action research," should reduce workers' vulnerability by involving them and their representatives in an informed and empowering process. These processes inform research design, method selection, and dissemination of findings. In our experience, participatory projects often benefit from qualitative activities such as interviews or focus groups of affected workers. Focus groups give the workers voice, inform many aspects of the research, and are an empowering experience for the worker-investigators. It is important that researchers understand the importance of these methods to the workers, while the worker partners need to understand the scholarly uses of these qualitative methods and to demand that the information obtained this way be considered as important as that collected using quantitative methods. For example, in our projects, the unions were involved in developing research questions for the Workplace Violence Intervention and workers helped to craft the survey questions from their focus group participation. These participatory approaches increased the likelihood that the project would address important and valid safety and health issues.

When evaluating the "beneficence" of a project, the CITI IRB training group suggests applying the following questions:

- Is the research design adequate? Can it be improved?
- What are the risks? Have they been minimized?
- What are the benefits? Have they been maximized?

It is important to remember that, by design, PAR processes strive to benefit the participating population. However, these features must be clearly communicated to the oversight boards because many IRB members, especially those with a traditional biomedical background, may not be familiar with PAR methods.

Justice

The Workplace Violence Intervention participatory project grew out of an effort by the three partner public employee unions to redress what their members experienced as an unfair employment phenomenon: workers are injured by the very clients for whom they were caring. The injuries often disable workers, sometimes to the point where they can no longer work and/or lose their jobs. Numerous injustices were documented, some of which drove the intervention project. Therefore, as is true with most projects like this, a spirit of justice infused this participatory research.

The following questions must also be considered to weigh fairness toward the subjects with the research goals:

- Does recruitment for the study target the populations that will benefit from the research?
- Does the recruitment unfairly target a population?
- Are the inclusion/exclusion criteria fair?

Our project partners jointly developed inclusion criteria for participating facilities and direct care workers. When direct care staff was recruited for focus groups and surveys, we made sure that we were available for all three shifts.

FURTHER CONSIDERATIONS

Involving workers improves communication and assures that the study's purpose and methods are not hidden from the worker community. Although this may increase the budget or delay the timeline, ethically it is the most appropriate strategy [8]. Participants should know who is sponsoring studies and be allowed to decide if they will participate, based on that knowledge. If the sponsor prefers to remain anonymous, potential participants need to have general information such as "private, for-profit company that does not wish its identity be known." When looking for participants, supervisors should not be study recruiters, nor should they know the identity of workers who choose to participate or those who opt out. For recruiting, use alternative methods such as posters, mailing, and telephone calls. No inducements should be offered to participate in the research. It is essential that "irresistible" incentives such as money or vacation time not be used to recruit study subjects [5]. On the other hand, in our experience, workers participating in research should not incur undue expense, so IRBs generally accept expense reimbursement and low value tokens of appreciation.

During informed consent, it should be made explicit that no "adverse employment consequences" will accompany participation or refusal to participate. Information is clearly stated so that all parties understand that autonomy is being preserved. If there are provisions for medical care in case of an adverse outcome, they also should be made explicit during informed consent.

Researchers must conduct research using the highest level of anonymity to collect and store data and report results. Coding, encryption, scrambling, and other techniques preserve anonymity and guard against accidental identification of individuals. We must pay the highest level of attention to issues of workers' confidentiality when anonymity is not possible. Another benefit of collaborating with an academic institution is that the principal investigator can keep records in a locked or password-protected system outside the workplace.

Communicating medical risk results to workers is another consideration. After struggling with the issue, the National Institute for Occupational Safety and Health (NIOSH) decided it has an ethical obligation to do so [9]. Findings can be disseminated in the peer-reviewed literature, the lay literature, at community meetings, in a union newsletter, at scientific meetings, and using web-based venues. The partners also may use findings in their own fact sheets and training materials. At the outset of one participatory project, the partners agreed to a procedure for reporting conflicting findings should any of them disagree about the interpretation of the results [10].

THE BOTTOM LINE

Researchers doing participatory research projects need approval from human subjects oversight boards. However, they should carefully document the participatory processes that ensure respect for persons (autonomy), beneficence, and justice. More IRBs need to hear that PAR is a strong and useful method that protects workers involved in occupational safety and health research.

RESOURCES FOR THE OCCUPATIONAL HEALTH RESEARCHER

1. Office for Protection from Research Risks
   http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm
2. Collaborative IRB Training Initiative (CITI)
   https://www.citiprogram.org/citidocuments/aboutus.htm

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Knowing June Fisher has changed my life. She has been an absolute inspiration for me. She freely shares her gifts of innovation and vision. She is relentless in her curiosity and insight, which results in her ability to develop novel approaches in tackling obstacles and problems. June is passionate and tenacious. When the rest of us call it a day and turn in for the night, June is just beginning to burn the midnight oil. She is a champion for social justice. As a nurse, I can say that June has been one of the greatest advocates for my profession when it comes to health and safety.

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