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FAST TRACK ARTICLE

Workers as Research Subjects: A Vulnerable Population

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Workers should be considered as a vulnerable human subjects research population since they require special protections. The Code of Federal Regulations "Common Rule for the Protection of Human Subjects in Research" does not offer adequate definition of this issue. Currently there is no formal ethical framework that addresses the unique vulnerability of workers (or former workers) who participate in research studies. This article addresses this concern and is based on a larger report published by the U.S. Department of Energy. Further, even though workers may be study subjects for legitimate political, social, and scientific reasons, meritorious science and adherence to the Common Rule must be the expectation. (J Occup Environ Med. 2002;44:801-805)

The protection of the rights and welfare of human research subjects is required whenever the United States government funds such research. The Code of Federal Regulations "Common Rule for the Protection of Human Subjects in Research," a regulation that has been adopted by 17 federal departments and agencies, defines the standards and processes researchers and research institutions must follow to safeguard human subjects.¹ There are special provisions in the Common Rule for the protection of vulnerable populations. In this paper we intend to show how workers can be considered as a vulnerable population and what special protections need to be afforded them, how the "common rule" does not offer adequate definition of the issue of workers as subjects, vulnerable or not, and lastly that while workers may be study subjects for political as well as scientific reasons, adequacy of the science and adherence to the Common Rule still must be the expectation.

Vulnerable persons are considered to be those who *are less able to defend themselves* in a given setting or situation. (The dictionary definition of vulnerable: capable of being physically wounded; open to attack or damage; liable to increased penalties.) In the world of human research regulations, this term is used to describe specific protections for children, fetuses, pregnant women, human in vitro fertilization, and prisoners. If we limit the term "vulnerability" to only those groups workers will not receive appropriate additional protection from harm.

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¹The U.S. Government requires that anyone conducting research involving human subjects adhere to "Common Rule." The Common Rule establishes guidelines and requirements to protect human subjects from bodily harm, social and economic loss, and from abuses of their dignity and autonomy. Although the Common Rule chiefly recognizes research that has the potential for physical or emotional risks to participants, it also protects volunteers who test new non-medical products and equipment, participate in behavioral surveys, enroll in workplace health effects studies, and provide samples for genetic research. The Common Rule gives research subjects the right to: (1) full and understandable information about the study and its risk and benefits, (2) choose freely whether or not they will participate, and (3) be assured that the study, as described, has been evaluated for its risks and benefits to subjects. It also supports an expectation of privacy in that study volunteers are told to what degree individual data about them will be kept confidential, and to what extent privacy can be assured.

The issue of "vulnerability" of a worker as a research study subject, or "paycheck vulnerability," occurs when studies are conducted in the workplace, especially in those workplaces that pose real or even perceived health and safety risks. Such workplace environments are as varied as chemical factories, hazardous waste cleanup sites, military settings, weapons production facilities, NASA spacecraft, power plants, and aircraft cabins. While each of these workplace exposures present different scenarios for the employee and provide different study opportunities, "vulnerability" is related to the fact that the employer often promotes participation of workers. The coercion potential in enrollment, or non-enrollment, for the study and/or loss of job, career, or benefit due to study findings is inherent in the relationship. This vulnerability issue is often a low profile and subtle issue. Unions on the other hand often promote worker participation on the expectation or hope that "entitlements" may follow. This, too, is coercion in a different sense.

Workers Are in Effect a "Vulnerable" Population and Subject to Employment Related Risks

Why is the worker vulnerable? Workers may experience management pressure to participate, not to participate, or to respond to a study in a way the employer or union may perceive as advantageous to the organization and/or to society.²

What are these risks? Risks from the impact of study findings may

²IRB-approved forms and documents and outreach materials that have been used in health studies of current and former workers at one DOE site are provided in the Attachments to "Creating an Ethical Framework for Studies that Involve the Worker Community". These examples may help researchers, funding agencies, and other stakeholders in worker studies develop similar materials adapted to their own specific needs, or, if appropriate, they may be used unchanged.

include the effects on individual entitlements, impairment of family relationships, possible threats to job retention, peer pressure, constraints to job advancement, and the ability to obtain and retain medical and health insurance. The findings from research studies also may present significant financial implications for individuals themselves, corporations, unions, or the government. Additional common vulnerability situations relate to pressure to consent to a study; the ability to give informed consent being compromised, diminished, or negated; or when the results of the study can affect livelihood or personal security of the worker or other workers. These risks, if properly addressed, can be effectively managed to avoid harming workers' rights. A Worker Study Participant Bill of Rights, Appendix 1, can be an effective tool and yardstick to meet this goal.

Why do we need these studies? Health and safety of workers has been improved over the decades through workplace studies that broadened understanding of exposure pathways and control methodologies. Improvement has also come from the development of better detection techniques and devices followed by subsequent standards and regulation. While such studies can provide an improved basis for the protection of worker health or safety, some studies, knowingly or inadvertently, may pose risk of harm to the physical, emotional, and economic well-being of the worker who elects to participate. This risk is especially evident when identifiable records are used without individual consent.

Why are these studies research and not operational improvements or observations? Studies using current workers or former workers as subjects become "research" when the intent of the study is to acquire health or exposure information (whether it is collected for the study or available in personnel records) that is to be used for purposes other

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than monitoring the health and welfare of that individual worker. (For the purpose of this paper, the term "workers" refers to both current and former workers.) In other words, a study becomes "research" when the intent of the project is to gather data and contribute to generalizable knowledge, to improve health practice, and extend benefits of the project beyond the individual study participants. In research, the data collected exceeds requirements for the care or diagnosis of the individual study participants or may be unrelated to care or diagnosis or uses non-standard/non-traditional workplace treatments or diagnostics.

The "paycheck vulnerability" relationship between subjects and employers is complicated by the ambiguous definition of "research" (45 CFR 46.102(d)),¹ the employee relationship with the employer's occupational medicine physician (analogous perhaps to the clinician-researcher conflict), by unstated or organizational agendas promoting studies to determine or to suppress risk, or to obtain "entitlements." Employer ownership of employee records and the absence of a human subjects protection system in settings remote in philosophy and mission from biomedical or traditional human subjects research increases the risks for participants and make studies more difficult to manage as human subjects research.

These potentially vulnerable populations deserve as much attention and protection as that given to subjects and patients involved in traditional biomedical research. Counter pressure to conduct these studies as merely routine occupational medicine or medical surveillance must be met with firm regulatory authority, a well-articulated description of benefits to the worker and to the study, and of equal importance, a plan for human subject review at an Institutional Review Board (IRB) of record.

Review by the Institutional Review Board (IRB) Helps Protect Against Vulnerabilities

The Common Rule also requires the establishment of a formally constituted Institutional Review Board (IRB) to oversee the protection of human subjects in research. The IRB examines each proposed study for its effects on subjects' rights and welfare. Wherever possible or feasible, local or site IRBs overseeing workplace studies should have a worker member or consultant and should review all proposed and continuing studies. When the researcher is not employed by an organization at the study site, the local IRB review may be coordinated with an IRB at the researcher's home institution, or if no other recourse, be the sole IRB of record. Because of the nature of occupational sites, the non-biomedical nature of the study and the fact that sites are not philosophically attuned to these studies, creative solutions may need to be found for IRB review, at an assured institution.

Although the seriousness of these concerns suggests the need for new approaches, safeguards, and scientific and ethical reviews specific to worker studies, currently there is *no* formal ethical framework that addresses the unique vulnerability of participating workers. In the absence of an established and functional ethical framework, apparent lack of knowledge or adherence to the Common Rule, possible insufficient organizational infrastructure, and despite the good intentions of the researcher, the employer, and other stakeholders, worker-subjects may be denied adequate protection of their autonomy, economic status, and/or social position. Review of such studies by a well-constituted IRB that includes a worker consultant or preferably a worker member safeguards against these risks.

The Research Plan and Communication with Stakeholders

Once the question of research versus "not research" has been settled, a human subjects research plan, should be given top priority. Such a plan is a review process that includes a scientifically meritorious protocol with a records management strategy, an objective, and a locale-sensitive method of communicating and interacting with the community and other stakeholders, and review by an "IRB of record."

In addition to the workers and the researchers, many other stakeholders have concerns and responsibilities that should be considered in a worker study. The employer, the union, the researcher's home institution, the IRB, the funding agency, the local community and larger public, and government at appropriate levels must actively work in partnership to follow the applicable guidelines and to attempt to reconcile potentially conflicting expectations or activities, whether valid or imagined. All stakeholders' roles should be considered in balancing the risks and benefits of the research. The IRB's role includes continued involvement in new issues as they arise during the study. Ideally, the research plan should recognize and involve all stakeholders from the outset. A complete research plan should assure accurate and full communication, appropriate scientific peer review and IRB review, and dedication of resources to ethical issues, as well as to the conduct of the study.

The rights and welfare of workers are best served when all stakeholders in worker studies understand the broad ethical principles that underlie the regulations that protect human subjects. The principles of *beneficence*, *justice*, *respect for persons*,³ and *nonmaleficence* establish the right of all research subjects to privacy, fair treatment, respect, self-determination, and protection from harm. To assure *respect for persons*,

the Common Rule requires that each research subject give voluntary "informed consent" to his or her participation in a study (see Bill of Rights following). For consent to be informed, participants must have adequate and understandable descriptions of the study purpose, know what is expected of them, and be informed of any benefits and/or risks they may experience. For consent to be voluntary, they must not face coercion regarding enrollment or reprisal for their decisions or loss of benefits from their study results. The principle of *beneficence* can be addressed with a health benefit to the worker, promise of detecting medical conditions, improving health/quality of life, safer working conditions or establishing entitlements claims. For worker subjects, *justice* includes allocation of resources, equitable choice of subjects and fairness to subjects, both potential and enrolled. *Nonmaleficence* implies doing no harm, and includes protection from loss of job, insurance or privacy. Historically, these expectations have not been explicitly implemented or addressed in workplace research. Some employers in the private sector, especially where hazardous materials are used or liability issues prevail, have voluntarily adopted scientific and human subject review systems. By Federal regulation adherence to these rules is not voluntary in public sector sites or federally funded studies, but this does not imply that all do comply.

All "stakeholders" must be made aware of and participate in addressing the special needs and issues that apply to research using *workers* as study subjects. The numbers of worker-related studies has increased significantly in recent years due to employee health and safety fears and/or political concerns about exposures and risks to health. Thus, ethical, social, health, or scientific issues that may be encountered during study conduct or after study completion (with either current and former workers as subjects) should be dis-

cussed with all stakeholders. All legal, scientific, and ethics protections must be explained and followed. The experience of NIOSH and CDC with workplace studies has been that the expectations of accepted ethical concepts as well as the regulatory standards of DHHS 45 CFR part 46 can be achieved. It is apparent that employers, with some exceptions, have not consistently applied these expectations to human subjects research. Substantial education on this issue in the workplace is needed.

Ongoing communication is another part of a well-designed study. The research plan also must allot time and resources for: (1) preliminary notification of the worker community; (2) periodic consultation among the stakeholders; and (3) dissemination of preliminary and final research results in a clear, open, and consistent manner. An environment of cooperation among stakeholders will improve the protection of study subjects and will also ensure the overall success of the study by increasing participation and preventing undue anxiety in the affected community. In communities where hazardous workplaces exist or did exist, multiple studies may be funded by one or many entities. These extensive activities, all focused on a single community, can cause great concern, apprehension, or false expectations among the populace and workforce. Candid communication, objective publicity, and shared involvement serve to minimize stress and make study results credible and scientific.

Communities or workplace sites where many risks or studies occur are encouraged to establish research information "clearinghouses" in order to announce, coordinate, and track worker studies. Open and comprehensive communications can define the approach, purpose, and expectations for all studies, avoid the replication of research, facilitate stakeholder cooperation, and provide clear research results so that community expectations can be satisfied.

Privacy: It May Be the Biggest Worker Issue of All

Hippocrates stated that "Whatever, in connection with my professional service, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret."

Researcher access to confidential records adds to the vulnerability of workers who participate in workplace studies. Inappropriate release of individually identifiable health or other personal data could adversely affect a worker's retention of a job, insurance, and other employment related benefits. To avoid or minimize these risks, the study design must include adequate safeguards to protect the confidentiality of the information collected. A plan for the proper management of study data and records should clearly define the: (1) control of the collected data, (2) use of data by others, (3) disclosure of that use to the subject, (4) use of personal identifiers, (5) who will/can have access/dissemination of study data and results, and (6) use or inclusion of study results in employee personnel or medical records. Where several studies are in progress with the same worker population, the risks to privacy and confidentiality are likely to increase, requiring even more diligence in the management of confidential data by investigators and by those monitoring the studies. Contact and consent materials and research plans must detail these safeguards, as well as limits provided by the law. The IRB, the researcher, and the subject must be informed of the limits and loopholes in the privacy laws governing workplace medical and research records, as well as ownership of data (that may or may not be property of the employee) and applicable state/local laws. The privacy situation currently is clouded by Federal Laws (HIPPA) and by many state laws that address specific situations such as genetic testing and privacy. Newer technologies and electronic transmission of medical records exceed historic protec-

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tions available for privacy. The Privacy Act of 1974 is problematic in its "routine user" access for "researchers" (and others) to obtain federally "owned" occupational medicine records. This clause is an easy conduit into workplace records.^{4,5}

The research use of genetic data and biological samples creates additional and complex ethical issues. Because of employment risk potentially associated with genetic screening or testing, some ethicists and researchers have argued that genetic screening or testing should have no role in the workplace. At a minimum, when studies or medical monitoring include the collection of biological samples, all planned future uses of the samples, identifiers, and the data obtained from the samples, must be fully explained and accepted by the participant before beginning the study. Federal or state guidance applying to use of biological materials in hospitals or biomedical studies also applies to the workplace.

Science and Ethics

While it may be unstated, it must be understood that good scientific design and methodologies are the foundation for worker health studies. If studies do not undergo independent peer review process they are less likely to produce useful results. If the science is poor, it is unethical to enroll any subjects, including worker subjects in the study. Worker health studies must be scientifically rigorous to justify the risks that have been discussed previously.

Summary

It must first be acknowledged that worker studies are subject to human subjects regulations. The application of human subject protections to employees (or former employees) who participate in workplace research is necessary for the welfare of the participants and to the credibility of the research. A considered and balanced approach must be used to address the unique risks to workers. Such an approach has been proposed in this

paper. Worker subjects must be protected at least as fully as any other "vulnerable" human subjects participating in research.

Appendix 1

Worker Study Participant Bill of Rights (A Model)

The rights below are the rights of every person who is asked to participate in a workplace study. As a study participant, you have the following rights:

1. To be told how your name was obtained, what the research or study is trying to find out and if you will be informed of your individual results.
2. To be told exactly what will happen to you in the study and whether any of the procedures, drugs, or devices to be used are different from what would be used in standard medical or occupational practice.
3. To be told about any frequently occurring and/or important risks, side effects, or discomforts that may happen to you in the research/study including risk of loss of privacy, insurance, or employment.
4. To be told if you can expect any benefit from participating and, if so, what that benefit might be and how realistic are the expectations.
5. To be told of the other choices or options you have and how they may be better or worse than being in the study.
6. To be allowed to ask questions and have concerns addressed before agreeing to be involved and during the course of the study.
7. To be told what sort of medical treatment is available if any complications arise and who will bear the cost.
8. To refuse to participate at all or to change your mind about participation after the study is started. This decision will not affect your right to receive the care you would receive if you were not in the study or affect your job in any way. The continued or further use of your data or samples after withdrawal from the study must be made clear.
9. To receive a copy of the signed and dated consent form.
10. To be free of employer or union or study investigator pressure when considering whether you agree to be in the study, to decline, or to later withdraw.
11. To know the name(s), title, and phone numbers of the Project Investigator(s). To be provided the required disclosures, if any, of possible conflicts of interest by the researcher or institution that may compromise the study or subject.
12. To know how the privacy of yours records and personnel information will be protected and what are the limits of this protection.
13. To know who will have access to your study records and results, and to know who will get results: employer, medical record repository, or other, and will that information be used in future studies? And whether data will be used in aggregate or individual results.

If you have any questions about the research study, you should ask the Project Investigator or the research assistant. In addition, you may contact the (*Name*) Institutional Review Board (IRB) of record for this study. The IRB is concerned with the protection of volunteers in research projects. You may reach the IRB office by calling (*Contact*), on (*Phone number*) between the hours of - & -, (*Days of week available*) by e-mail (*E-mail address*) or in writing (*Address*).

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