CHAPTER 2

FOUNDATIONS OF AN ETHICAL FRAMEWORK

Key Points:

- **The rights and welfare of workers are protected when everyone involved in worker studies understands and applies the Common Rule and the ethical principles of beneficence, justice, and respect for persons as described in The Belmont Report and many professional codes of ethics.**

- **It is expected that workers who are asked to participate in a study must not face coercion or reprisal for their decision to participate, not to participate, or to withdraw from a study. In the informed consent process, they must receive adequate and understandable descriptions of the study purpose, what is expected of them, why they were selected, and any benefits and risks they may experience if they choose to participate.**

- **All worker studies should undergo local review by an Institutional Review Board familiar with both the work force and the workplace.**

Establishing the Foundation

The Belmont Report: The Principles of Beneficence, Justice, and Respect for Persons

The Belmont Report, issued in 1978 by the National Commission for the Protection of Human Subjects, provides the ethical basis for worker studies. The report identifies the fundamental ethical principles that should govern research involving human subjects—the broad principles of ***beneficence***, ***justice***, and ***respect for persons***. These principles, as defined in The Belmont Report, apply to all research studies involving human subjects, including those carried out in occupational settings.

The Belmont Report, issued in 1978, defines three basic principles that apply to all research involving human subjects. These are the principles of *beneficence*, *justice*, and *respect for persons*.

1. ***Beneficence*** is the obligation to do no harm to persons and to protect them from harm by maximizing possible benefits and minimizing possible risks. Researchers must acknowledge that damage in the form of discomfort and harm can take place at the physical, emotional, social, and/or economic levels. In worker studies, as in others, there is a tendency to discount emotional, social, and economic stress factors, in part, because they are difficult to assess.

   There are five levels of discomfort or harm that a researcher should consider when assessing the effects of a worker-study. There may be: (1) no anticipated effects, (2) temporary discomfort that ceases with the termination of the study (sometimes called minimal risk), (3) unusual levels of temporary discomfort typically lasting beyond the study termination, (4) risk of permanent damage, and (5) certainty of permanent damage.

2. ***Justice*** is the mandate requiring fairness in the distribution of burdens and benefits that is often expressed in terms of treating persons of similar circumstances or characteristics similarly. Injustice occurs when the selection of subjects results in an uneven distribution of risks or benefits. Researchers should avoid inappropriate, or the appearance of inappropriate, exclusion. For example, the exclusion of workers based on gender or race—often explained away due to small sample size—might introduce what is, or is perceived to be, a bias on the part of the researchers or funding agencies, or it may yield skewed scientific results.

3. ***Respect for persons*** is essential to ensure that individual autonomy is respected and that those persons with diminished capacity are protected. In order to preserve autonomy, subjects must be fully informed about a study before it begins. Covert data collection, deception, and misinformation all deny autonomy.

   Another way in which autonomy may be denied is through coercion—real or perceived. Coercion is the threat of physical, economic, or social harm but can also take the form of excessive reward for participation. Workers must be free to

participate, or not participate, in the study or to withdraw from the study at any time through their own volition.

Fear of economic loss or other workplace disadvantage is a powerful coercive agent whenever the interests of employees and the employers are at odds. Social coercion or stigma may also occur when worker, union, or community interests are at odds. Researchers and IRBs should be alert to coercive influences for any studies that have the potential to affect the cost of doing business, possibly give the business a competitive edge, or word the research question to be examined in a controversial or inflammatory manner.

Researchers have several tools available to ensure that the ethical principles of The Belmont Report are observed. These include the use of an appropriate, informed consent, Institutional Review Boards (IRBs), and codes of ethics.

Informed Consent

Informed consent is defined as the research subject's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. Informed consent processes and documents must meet the requirements of the Common Rule and may not be used to request that research subjects waive legal rights nor exempt the investigator, sponsor, or institution from liability for negligence.

INFORMED CONSENT: A research subject's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a developmental diagnostic, therapeutic, or preventative procedure. Informed consent must meet the requirements of the Common Rule, and subjects may not waive or appear to waive their legal rights or release, or appear to release the investigator, sponsor, or institution from liability for negligence.

Informed consent is the heart of the Common Rule and is essential for the protection of human subjects in research. Providing informed consent respects the individual's autonomy and right to make choices. Because participation in a study must be voluntary, the possibility of coercion—real or perceived—is a serious concern that must be protected against.

Research subjects are truly informed when they have been given all of the information they need about a study to decide whether or not to participate and when they have received that information in an atmosphere that fosters a free and voluntary decision. Careful attention needs to be given to: (1) the person who obtains consent, (2) the timing of consent, (3) the manner in which consent is sought, and (4) the potential for real or perceived coercion. For instance, a worker's personal supervisor or anyone else with authority or influence should not be involved in obtaining consent or in subject recruitment.

Another factor affecting worker studies is that health-related occupational research is often conducted with a worker population bound by a contract that establishes obligations upon both employers and employees. This contract will influence the way the research is conducted. It will also influence the worker's attitude, perception, and response to an "offer" to participate in such studies. Moreover, the very fact that a health study is being conducted, regardless of outcome, can cause employees to perceive a threat to their present or future employment.

Criteria for the Informed Consent Process and Documentation

A well-designed process for obtaining informed consent will, at a minimum, meet the criteria established by the following questions:

- Has the researcher provided a comprehensive description of the research in lay terms?
- Has the worker had time to consider the proposal?
- Has a knowledgeable person—able to assure worker understanding—explained details of the worker's participation and study procedures?
- Have foreseeable risks or discomforts been presented in a realistic, open way that encourages questions from the worker? Have the possibilities of unforeseen risks been explained?
- Does the worker understand how the research methods will protect subjects from physical, social, or economic risks arising from the study?
- Have benefits to the subject and/or the public been explained?
- Where applicable, have alternative courses of treatment been explained to the worker?
- Has compensation for cost to subjects been addressed?
- Is a feedback system in place to keep workers informed of progress and results?
- Has the worker's preference for right to know, *or not know*, individual study results been determined?
- Has the worker been assured that best efforts will be made, though not completely guaranteed, to maintain confidentiality (the extent to which confidentiality can be protected) and privacy (up to the defined limits)?
- Does the worker understand the use of pre-existing data or previously collected tissue samples and any foreseeable potential future use of data and/or tissues?
- Has the worker been assured that participation is voluntary and that he or she has the freedom to withdraw at any time without penalty or loss of benefits to which he or she is entitled?
- Does the worker understand what recourse he or she has should participation be coerced?
- Have the project manager, principal investigator, IRB contact, and counselor been identified and their functions described?
- Has a copy of the consent form been provided to the worker?
- Has the worker been given the name and telephone number of someone to contact about questions or concerns?

Whether the "coercion" to participate is real or perceived has little bearing on the matter.

Because of the importance of informed consent, IRBs should focus strongly on the informed consent process and documentation when they review research protocols. Careful attention to informed consent by the researchers, the IRB, and others who are involved in the project is especially important to ensure that subjects are fully aware of the unique risks to which they may be exposed during the course of the research.

An agreed-upon, informed, and sensitive approach should be the primary concern and overriding duty among researchers, managers, and unions (or employee representatives) in assuring that the worker is truly making a free choice to participate, not to participate, or to withdraw from a study to which he or she may have initially agreed.

In some instances where there is a body of existing data (data collected before the research study in which the data are to be used was conceived), the data apply to persons with whom contact has been lost, or deceased individuals are involved, informed consent may not be feasible or required. In such cases, before obtaining access to that data, the researcher must seek the advice and concurrence of the local IRB and/or the federal privacy officer controlling access to the occupational data.

The Role of the Institutional Review Board

All projects with human research subjects must be reviewed by an IRB—a formally constituted multi-disciplinary group at the research location and possibly at the research institution—as required by the Common Rule. Based on the members' assessment of the risk/benefit ratio to human subjects, and to ensure that worker rights and welfare are fully protected, the IRB has the authority to approve, deny approval, suspend, or terminate previous approval of research.

Institutional Review Board (IRB): The IRB is a formally constituted group of individuals responsible for reviewing all research involving human subjects covered by an assurance (agreement with the funding agency) for a given institution or site. While IRB membership is typically small in number and may not include all stakeholders, workers and the community should be represented on the board. The IRB is responsible for assessing the risk/benefit ratio to human subjects to ensure that their rights and welfare are fully protected according to the Common Rule. The IRB has the authority to approve, deny approval, suspend, or terminate previous approval of research.

Coordination of Reviews

Use of local IRBs is the benchmark for each workplace study and should, therefore, perform the review of all worker studies in their work force or community. Researchers, however, may also be required to submit their research plans and progress to their own IRBs. When this is the case, it is possible to establish cooperative agreements between the two IRBs after allowing the decisions of the local IRB to take precedence.

All worker studies should undergo site reviews by IRBs familiar with both the local worker population and with the work conducted at the site.

Other mechanisms to facilitate coordination between two IRBs may include a memorandum of understanding that clearly defines the primary IRB authorities and responsibilities. When a local IRB is presented with numerous worker studies, a subcommittee of the established IRB—or a separately constituted IRB—may be established to review and approve studies where two IRBs are involved.

Regardless of its role, each IRB should have among its members at least one person not affiliated with any of the stakeholders and at least one worker-member from the worker-study population. Expert counsel can and should be used for all situations in which the IRB membership is not able to address an issue adequately.

Codes of Ethics

Existing professional codes of ethics also provide useful models, ideas, and references that can be used to: (1) develop worker study programs and approaches for addressing the risks to workers, (2) measure research professionals against their own codes, or (3) provide guidance in developing new codes. Examples include the codes of the American College of Occupational and Environmental Medicine, the Human Factors and Ergonomics Society, the International Society for Environmental Epidemiology, and the Council for International Organizations of Medical Sciences (see Appendix E). However, none of the current professional codes fully address the special needs and issues of worker studies, and new models need to be created.