APPENDIX B

THE NIOSH APPROACH TO WORKPLACE STUDIES

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What is NIOSH?

The National Institute for Occupational Safety and Health (NIOSH) was established by the Occupational Safety and Health Act of 1970. NIOSH is part of the Centers for Disease Control and Prevention (CDC) and is the only federal agency whose sole mission is to conduct research and make recommendations for the prevention of work-related illnesses and injuries. NIOSH's responsibilities include:

- Investigating potentially hazardous working conditions as requested by employers or employees.
- Evaluating hazards in the workplace, ranging from chemicals to machinery.
- Creating and disseminating methods for preventing disease, injury, and disability.
- Conducting research and providing scientifically valid recommendations for protecting workers.
- Providing education and training to individuals preparing for or actively working in the field of occupational safety and health.

Although NIOSH and the Occupational Safety and Health Administration (OSHA) were created by the same Act of Congress, they are two distinct agencies with separate responsibilities. OSHA, a regulatory agency under the Department of Labor, is responsible for establishing and enforcing workplace safety and health regulations. NIOSH was placed under the Department of Health and Human Services (HHS) and was given the responsibility of conducting research, consultation, and training related to occupational safety and health. NIOSH is, therefore, engaged in both public health research and practice.

NIOSH seeks to identify the causes of work-related diseases and injuries and the potential hazards of new work technologies and practices. With this information, NIOSH determines new and effective ways to protect workers from chemicals, machinery, and hazardous working conditions. Finding new ways to prevent workplace hazards is the job of NIOSH.

NIOSH public health practices involve the conduct of health hazard evaluations (HHE). In this case, NIOSH professionals perform assessments of specific work places by means of industrial hygiene and medical/epidemiological evaluations for the purpose of identifying health-threatening conditions and recommending immediate, site specific corrective actions.

Because NIOSH research studies and NIOSH health hazard evaluations have different objectives, they are reviewed and administered differently. NIOSH research, in addition to undergoing a scientific peer review, is subject to NIOSH's Human Subject Review Board (HSRB) to assure compliance with federal regulations and ethical standards pertaining to human subject research. Health hazard evaluations, as targeted public health interventions, are guided by established professional practice standards of conduct.

The NIOSH Human Subjects Review Board

The NIOSH HSRB operates under and is assured by HHS Protection of Human Subjects regulations (45 CFR 46). The current board includes 15 members representing a range of professional backgrounds—physicians, engineers, psychologists, audiologists, toxicologists—as well as three outside members including an educator, a practicing occupational medicine physician, and a labor attorney.

An assigned member who acts as the lead reviewer presents a study protocol to the board. In addition to summarizing the purpose and methods of the investigation, the lead reviewer also discusses the potential risks and benefits to the study participants and describes any relevant issues raised by the scientific peer reviewers. Special attention is paid to:

1. The method and materials used for participant recruitment.
2. The informed consent process and documentation to assure compliance with the elements of informed consent as specified in 45 CFR 46.
3. Records management systems and confidentiality safeguards.
4. Procedures for participant notification and/or general debriefing.
5. Peer reviewers' comments to ascertain potential risks and benefits as well as special concerns regarding debriefing, records management, etc.

HHEs - Research Versus Non-Research

Health hazard evaluations are distinguished from general research projects because, in the former, NIOSH has received a request to determine whether a particular exposure poses a health risk or whether an identified health effect is due to an occupational exposure. ***Typically, this task is not research, but rather the public health equivalent of diagnosis and treatment*** (i.e., documenting the problem and recommending corrective and preventive measures). Nevertheless, some HHEs provide the opportunity for research as an adjunct to the main task, or even as the only means of accomplishing the task. Consistent with CDC policies, NIOSH's HSRB distinguishes "clinical" HHEs from "research" investigation. An HHE is generally reviewed as a research investigation if it involves any one of the following three conditions:

1. A "control" group that would not derive the same benefit from the procedures as the "exposed" group.

2. The testing of a "research hypothesis." The attempt to determine whether a health effect is associated with an exposure at a particular workplace is the purpose of the HHE program; for the purpose of categorizing the HHE, it is not considered the testing of a research hypothesis.
3. A study design intended primarily to gain generalizable knowledge rather than to provide diagnostic or other direct benefit to the participants.

When a study cannot be clearly defined as research or non-research, NIOSH will err on the side of calling the proposed study "research" and adhere to research protocols.

An HHE is a clinical evaluation—as opposed to research—if it involves ***none*** of the preceding conditions. Such an investigation is not subject to HSRB review. Nevertheless, even non-research HHEs may be submitted to the HSRB if ethical quidance is requested. This may involve:

1. A questionnaire that solicits personally sensitive information (i.e., information that has potential adverse social, economic, or legal consequences if disclosed).
2. Any medical exam or medical procedure that is invasive, venipuncture expected, or involves more than a "minimal risk" of harm.
3. Any medical test that is not ordinarily used in a clinical practice, including occupational medical practice.
4. Any "experimental" medical test.
5. Any device, test, or material subject to Food and Drug Administration approval but which has not been approved for the proposed use.
6. Participation by person under 18 years of age.
7. Participation by pregnant women if either of the following apply: pregnant women are the focus of the study or are otherwise sought out, or any of the procedures may pose a risk to the fetus.
8. Payment or other compensation for participation.

Additionally, in order to avoid extraneous controversy, a proposed study might be submitted for HSRB review solely because of its newsworthiness or its unusual political interest, even though it is clearly "clinical" and does not involve any of the above considerations.