

## **PREFACE**

### **WORKING TOGETHER IN A CONSTRUCTIVE ENVIRONMENT**

Studies to assess the health effects that may be related to occupational environments and workplace exposures provide data essential to reducing or preventing illnesses, injury, or disease among current and future workers. We have concerns, however, that unless their rights and welfare are fully protected, collecting these data may expose participating study subjects—the workers—to significant personal, professional, and economic risks. There is also the concern that, in some cases, worker studies are not recognized as research.

Although the concerns imply a need for approaches, safeguards, and scientific and ethical reviews specific to worker studies, there is currently *no* formal ethical framework that addresses the unique vulnerability that participating workers face. In the absence of an established and functional ethical framework, and despite the good intentions of the researcher, the employer, and other stakeholders, worker-subjects may be denied adequate protection of their personal autonomy, economic status, or social position.

The purpose of *An Ethical Framework for Studies That Involve the Worker Community* is to raise the awareness of all stakeholders to the special needs and issues that apply to research using *workers* as study subjects. The creation, dissemination, and use of this report has become important as the numbers of worker-related studies at the Department of Energy (DOE) and elsewhere has increased significantly in recent years. This document describes the ethical aspects that may be encountered in studies with both current and former workers as subjects, and it presents recommendations for the design and conduct of these studies to ensure that workers are protected legally, scientifically, and ethically. This paper also presents recommendations for establishing an environment of stakeholder cooperation and collaboration that will foster the ethical conduct of such studies. Examples of model documents that have been approved by Institutional Review Boards (IRBs) and successfully used in worker studies are also provided.

The observations and suggestions in this report reflect the expertise and experience of people throughout government, academia, and industry, including workshop participants in a 1997 DOE Office of Science-sponsored workshop on the topic of an ethical framework for worker studies. Contributors to this report include workers, employers, researchers, DOE facility contractors, IRB members, occupational physicians, unions, and other governmental agencies, many of which have potentially conflicting roles, concerns, and interests in worker studies.

Although this document focuses on issues of concern to DOE, we hope that you will find these recommendations and resources useful in building an effective ethical framework for any worker study. We invite you to share your comments and suggestions as we continue our efforts to establish guidelines for worker studies suitable for use by all—federal agencies and the private sector.

Dr. Susan L. Rose, Manager  
Human Subject Research Program  
Office of Science  
U.S. Department of Energy