# CHAPTER 6

# IN CONCLUSION: PLANNING AND CONDUCTING ETHICAL WORKER STUDIES

**Key Points:**

- **Ethical considerations unique to worker studies must be addressed from planning through publication of the results. These considerations include the need for early notification of the purpose of the study, obtaining a fully informed consent, timely feedback of interim and final study results, and supporting each worker's freedom of choice to participate, not participate, or withdraw from the study.**

- **The protection of the worker-subjects and the success of the project depend upon a collaborative relationship established early in the design and development of a project with the involvement of the workers, the researchers, the employers, the unions, the community, and other stakeholders.**

- **Communication and coordination of all local worker health studies through an information "clearinghouse" at the local or agency level may be a good mechanism to improve coordination and success of worker studies. It would reduce duplication and multiple requests for individual workers to participate in similar studies, and could alleviate worker and community concerns by providing educational and comprehensive information.**

## Introduction

The ethical foundation for worker studies has been established, and the following topics have been discussed:

1. Workers as human subjects in occupational studies.
2. The requirement for the ethical and regulatory protection of workers as subjects in worker studies.
3. The impact of genetics testing and screening on privacy issues.
4. The need for maintaining the privacy and confidentiality of worker-related data, identities, and biological samples.
5. Stakeholders concerns and responsibilities.

This chapter is intended to provide summary guidance for designing and planning a worker study, taking all of the above topics into consideration.

Proper planning is the key to ensuring that each of these areas is thoroughly considered and properly addressed during the design and conduct of the study. Proper planning is essential for a study that is not only ethical but that also produces scientifically sound results. These same considerations must be monitored and adhered to during the conduct of the study.

In the early phases of study, collaboration among stakeholders should be used to develop a comprehensive, well-defined methodology that takes into consideration their diverse concerns. Involving all stakeholders during planning of worker studies helps assure complete understanding of concerns and responsibility of all parties and reduces the chances of unexpected obstacles or errors in the study. For example, involving the local community (which includes workers and their families) in advance is of major importance in addressing public concerns about the research.

The study methods should also consider the possibility of using the study data or specimens for other purposes, such as another study, even though the information initially will not be collected for that purpose. The informed consent process must reflect the possibility of the “re-consenting” subjects versus limited or blanket consents to facilitate later ethical and legal access to the information and/or samples collected. The study methods should address planning, reviews, implementation, management, reporting, and publication of results.

Human-subject study reviews are necessary to ensure that workers participating in the studies are fully protected. The study methods and progress reviews should include:

- Independent, scientific peer review to validate the merit of the study.
- Human-subject reviews by the IRB. (The IRB should include at least one worker as a member, to address the interests of the worker subjects.)
- Review of information and plans by other groups affected by the study to assure that stakeholder interests are being addressed completely and fairly.

- Continuing required IRB reviews during the course of the study to ensure adherence to the approved research plans as well as for notification of noncompliance or adverse effects.

## Study Planning: Guidelines

Worker studies should be planned to ensure that:

- Ethical issues are fully examined.
- All stakeholders—particularly the workers—are aware of the project as early in the planning as possible.
- Early discussion takes place on *all* stakeholder needs and desired goals.
- A scientific peer review is completed.
- An IRB review takes place before work begins.
- Systems to share information and results with all stakeholders—as appropriate—are established.
- Research goals, methods, and anticipated results are well-defined and clearly understood by all parties, and not merely a "fishing expedition."
- The research design clearly leads to the desired research goal(s).
- Workplace improvement and health benefits to the workers are considered significant goals.
- The language used, especially the language in the consent forms, is understandable to all stakeholders.
- All costs, including IRB and medical records review, are forecast and included.
- Available and potential sources of health and research data are identified.
- The use of medical records are addressed and approved by the privacy officer and the IRB.
- Research records will not be included in medical records or that they will not be included in medical records without the consent of the participants.
- Future use of data or biological samples is addressed, and the appropriate consent is obtained.
- Plans have been made for treatment, ongoing monitoring, or medical referral of employees found to be ill in the course of the study.
- Communication with stakeholders occurs in an environment that is non-threatening, supportive of the workers, and conducive to open discussion.
- Protection of privacy and confidentiality of participant data and results is well addressed.

## Privacy Act Limits Worker's Option to Not Participate

Even though individual employees may be free to participate in—or withdraw from—a study, there may be serious implications when there is a legislative or organizational mandate to participate in ongoing medical surveillance. This is especially true if there is the likelihood that the surveillance data will be used later as part of a research study. For

example, medical surveillance may be required for the safety of the worker in his or her current job.

In this case, the worker may have ***no*** option to agree or to decline to participate in later health studies if those studies are based solely upon Privacy Act-protected records and if the IRB has granted the researchers a waiver of consent. Access to those records is granted or denied by the government agency according to whether or not the study fits the criteria for "routine use."

However, in a study **not** conducted under the provisions of the Privacy Act, with the subject's consent of access to personal medical records, a subject may elect to withdraw from the study. If a subject withdraws from a study, the subject, the IRB, and the researcher must consider the following issues:

- Can or should the data already collected be removed or be retained?
- Will the data be handled in the same manner as data obtained in the rest of the study?
- What impact does the withdrawal have on the statistical validity of the study?

These issues should be considered during the formulation of the informed consent process and in the study design.

## Study Implementation

Prior to and after a worker health study has been reviewed and funded, the organization responsible for conducting the study has a number of ongoing responsibilities to assure that workers continue to receive timely information about the study. The organization must:

- Notify all stakeholders about the study.
- Continue to educate and inform all stakeholders.
- Strive to get "buy-in" from workers.
- Obtain authorization to get worker data.
- Develop and administer the worker informed consent, which addresses previously defined issues.
- State clear goals for data usage.
- Provide all information in clearly written form suitable for layman's understanding.
- Provide follow-up information to study subjects when authorized and appropriate.
- Schedule the overall study process with adequate time for implementation.
- Schedule all continuing reviews as agreed upon.
- Manage biological samples and sample data ethically, legally, and in accordance with the approved protocol.

## Early Notification and Informed Subjects Support Study Implementation

> Aware, educated workers are better able to determine their level of participation in research studies and should not be as vulnerable to other issues and concerns.

Early notification and education of all stakeholders is imperative to the success of worker studies, but it is most important for the workers who are the subjects of the research. Well-prepared, informative IRB-approved outreach and educational materials describing not only the study procedures but also the objectives and the implementation of the study are extremely valuable (see the attachments for examples of, or materials suitable for, IRB use).

"Notification" does not end with the worker's consent to participate. As information becomes available, when possible and as part of the study design, it should flow to each participant throughout the course of the study. For example, participants who have requested to see their personal data from the study should be provided with this information as soon as the data analysis is complete. (See also "Dissemination of Data and Results" in Chapter 4.)

## Establishing an Environment of Cooperation Among Stakeholders

Identifying the risks, protecting workers who participate in studies against these risks, and fostering an environment in which all stakeholders in the research understand its range and its limits, adhering to those limits, and working together are serious

***Guidelines for Creating a Cooperative Environment for Worker Studies***

- Involve all stakeholders during proposal planning of worker studies to assure complete understanding of concerns and responsibility of all parties.
- Involve the community (through town meetings, local media, and publications) to assure the public that their concerns about the research will be seriously considered in planning the study.
- Include ethicists and workers subjects (or worker representatives) on advisory committees and IRBs to address worker concerns.
- Request adequate funding in the worker study proposals to support the required coordination and review activities.
- Use expert counsel in special areas where issues related to worker studies are not commonly addressed or understood.
- Establish, as part of the study plan, a process for continuing review of the worker study, its protocol, privacy protections, and progress.
- Work with relevant professional groups to incorporate worker study ethics guidance into their existing codes of ethics or to implement those that already exist.
- Establish a focal point at each work site where numerous worker studies currently funded may be administered independently.
- Establish a working group with broad stakeholder participation to interact with and guide the study as it progresses.
- Disseminate intermediate and final study findings to stakeholders, including worker-subjects, at the earliest possible time, consistent with "good science."

responsibilities for all organizations sponsoring and conducting studies involving workers. An environment of cooperation and collaboration among all stakeholders in a worker study must be established early in the process of study development to ensure the protection of workers and the success of a study.

Contributors to this report have identified the following recommendations for creating an environment conducive to the planning and performance of successful worker studies. Some of these recommendations apply to the structure of IRBs, while others apply to the processes to be followed at sponsoring and overseeing organizations.

## Proposed "Clearinghouse" Model

Local and agency-wide information "clearinghouses" to coordinate and provide information on past, current, and proposed worker health studies may avoid unnecessary duplication of work and may improve communication on and acceptance of future studies.

The multiplicity of government-sponsored worker studies and data collection activities, especially at some politically sensitive or suspected hazardous work sites, suggests a need for a focal point or "clearinghouse" for study-related information at both local and federal levels. Coordination through such clearinghouses could help ensure the success of each study, increase cost-effectiveness by avoiding unnecessary replication, and reduce the anxiety or even hostility workers and communities may feel when they are repeatedly asked to participate in studies, or hear rumors about undocumented studies and their effects.

In addition, the clearinghouse function could greatly enhance communications among stakeholders at various sites. The clearinghouse could also serve as a source of information about the purpose of studies, the types of subjects to be recruited, points of contact, a timetable for each study, and the types of study results that are anticipated. A clearinghouse would supplement education and communication and would not be a substitute for the review of research by an IRB.

In summary, the "clearinghouse" concept could effectively satisfy the communication and informational needs and expectations of the work-site personnel and other citizens who, in the past, may have been ill-informed—even misinformed—regarding studies occurring within their community.