

## CHAPTER 5

### STAKEHOLDERS: THEIR INTERESTS, CONCERNS, AND RESPONSIBILITIES

#### Key Points:

- Each worker study involves multiple stakeholders in addition to the researcher and worker.
- Stakeholders' interests in worker studies, both shared as well as conflicting concerns, that must be identified, discussed, and resolved.
- Stakeholders' *knowledge and acceptance of responsibilities* and their active participation in the worker-study process are essential to protecting the rights and welfare of workers as research subjects.

## What Are Stakeholders?

A “stakeholder” in a worker health study is an individual or a group with an interest, or “stake” in the conduct or outcome of the study. When workers participate in research studies, the list of stakeholders is long and includes, at a minimum, workers, the employer, insurers, researchers and their institutions, multiple levels of government, funding agencies, the public/community, unions, Institutional Review Boards (IRBs), and occupational medical professionals.

The concerns and issues important to each stakeholder are listed in this section. These should be noted and addressed early in the research planning to ensure their inclusion in the overall design, conduct, and publication of the study.

## Stakeholders: Working in Partnership

**The preeminent concern for all stakeholders is the protection of the rights and welfare of worker-subjects in research studies.** Stakeholder concerns may include access to workers (the researchers), maintaining productivity in the workplace (the employer), and assuring compliance with federal regulations (federal authorities). Thus, there is the potential for conflict among groups of stakeholders, and such conflict may not always be in the best interests of the worker. There is a need to balance the proposed research with each stakeholder’s interests.

Several considerations are important in protecting the rights and well-being of study subjects and assuring that stakeholders in the studies are able to protect valid interests. These include:

- Recognizing the diverse interests and concerns of other stakeholders.
- Clarifying responsibilities of all participants.
- Agreeing to work cooperatively with one another to achieve the best possible results for the study and all participants.

## Interests, Concerns, and Responsibilities Common to All Stakeholders

There are interests, concerns, and responsibilities shared by all stakeholders that should be acknowledged, accepted, and/or agreed upon during the initial planning stages of the worker health study and re-examined throughout the study process.

Shared interests and concerns applicable to all stakeholders are to ensure:

- The protection of the rights and welfare of worker-subjects.
- Early notification all stakeholders—particularly the worker population—of studies.
- Early involvement of all stakeholders, including the worker population, in the design and development of the study.

- All stakeholders understanding the objectives and proposed methods of the study.
- All stakeholders understand and comply with human-subject study ethics and regulations.

Shared responsibilities applicable to all stakeholders are:

- To ensure that the study has scientific merit and/or is subject to rigorous peer review.
- To be informed about the research topic and procedures.
- Work to achieve consensus with other stakeholders when conflicts are apparent.
- To provide notification and project information to other stakeholders.
- To participate actively in the development, design, and conduct of the study.
- To fulfill these responsibilities throughout the life of the study.

**Stakeholders** in worker studies share responsibilities to recognize one another's interests and concerns, to clarify their own individual responsibilities, and to agree to work cooperatively with one another to achieve the best possible results for all parties.

## Interests, Concerns, and Responsibilities Specific to Individual Stakeholder Groups

Each stakeholder involved in worker studies is ultimately responsible for fully understanding his or her role in protecting workers who are subjects of research. The issues, concerns, and responsibilities specific to individual stakeholders are described below.

### Workers

**Workers have the most to gain<sup>3/4</sup> and lose<sup>3/4</sup> from worker studies. Their interests and concerns should take precedence over the interests and concerns of other stakeholders.**

Interests and concerns applicable to workers and worker-subjects include:

- The freedom from coercion/pressure to participate, decline or withdraw—whether real or perceived.
- Perceived or actual threats to job security, future employability, pension, or medical benefits.
- Early and complete notification of studies planned or conducted.
- A full understanding of the research protocol and purpose.
- Privacy and confidentiality of personal records, data, or tissues.
- The possible perception of being exploited when they are the subject of an excessive number of research studies (considered as guinea pigs).
- Job security and potential impact on job advancement.
- The extent of involvement in the program.
- The impact of time away from job or lost time.
- Possibility of injury or pain.
- Possibility of psychological impact.
- Continued or future insurability.
- Potential impact on family.
- Potential social stigma (personal or family).
- The availability of counseling.
- An awareness of available methods to resolve concerns.



Responsibilities of workers and worker-subjects include that they:

- Read pertinent study information.
- Read and understand the informed consent documents and study materials.
- Know and understand one's rights as a research subject.
- Abide by protocol (if the individual agrees to participate in the study).
- Confirm that they understand the subject matter with study experts.
- Ask questions.

- Suggest changes to the study or informed consent as needed.

## Employers

Employers are often concerned—if not threatened—by the possible cost and economic impact to their business due to the publication or dissemination of worker health study results. However, most employers recognize that early detection of identifiable health problems typically costs less over longer periods of time. The employer’s attitude and cooperation are important to achieving broad worker acceptance and participation in a health study and successful study outcomes.

Interests and concerns applicable to employers include:

- Early notification and continued involvement in study design and conduct.
- Protection of proprietary or sensitive information.
- Costs, including start-up, lost productivity, insurance, use, and copying of records.
- Protecting each employee’s privacy.
- Maintaining productivity and profit.
- Potential liabilities such as:
  - Study findings that may be (or appear to be) detrimental to the company.
  - Obligations or worker compensation that might result from the study findings.
  - Third party issues (insurance).
  - Public perception of the company.
- The possible misuse or misunderstanding of data or study results.
- Possibility of a poor experimental design.
- The assurance that the study is “good science.”
- The possibility of erroneous or unusable results.
- Protecting employees and their well being, as well as maintaining a healthy workforce.



Responsibilities of employers include that they:

- Assure that the worker-study process is thoroughly understood by management.
- Require that the study undergo scientific peer review.
- Participate in the development and design of the study.
- Assess the risks and benefits to both employees and employers.
- Know and understand the rights of subjects.
- Assure that the worker community has full knowledge of the research study.
- Know and understand protocols—clearly understand the conditions of the study.
- Abide by the protocol.
- Follow through with all commitments.

- Maintain an active role and relationship with researchers.
- Assure that workers, unions, and the communities are aware of studies.
- Establish valid reporting relationships.
- Fund and encourage occupational health surveillance of the work force.
- Establish and maintain an effective program that protects employee confidentiality and privacy for all records.

## Unions

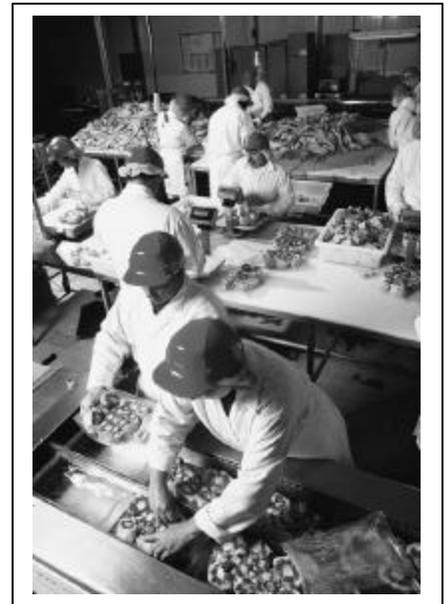
Unions may take an active role in protecting the interests of workers. Because a union often serves as a major source of information and influence on members, the union is an active stakeholder in any study involving its members, and the union's cooperation is essential. Union goals, however, may not be identical with those of the individual worker-subjects. Unions may also conduct research, resulting in a potential conflict with their traditional role.

Interests and concerns applicable to unions include:

- Early notification and involvement in study planning.
- Assurance that the worker community has full knowledge of the research.
- The ability to assure that worker concerns are addressed.
- The ability to adequately represent the interests of their organization and their members.
- The ability to participate during the life of the study.
- The ability to obtain notification of current and proposed programs.

Responsibilities of unions include that they:

- Protect the interests of their members.
- Assess risks and benefits to their members.
- Be aware of studies involving, and available to, workers.
- Be aware of special ethical issues related to worker studies.
- Assure that the study has scientific merit through peer review.
- Know and understand the rights of subjects.
- Assure that the worker community has full knowledge of the research.
- Know and understand protocols, and that they clearly understand the conditions of the study.
- Abide by protocol.
- Follow through with all commitments.
- Maintain an active role and relationship with the researchers.
- Maintain their independence.
- Establish valid reporting relationships.



- Encourage policies and procedures that promote the overall occupational health of the workforce.
- Communicate results and data accurately to the workers.

## Researchers

**Researchers must take the lead role in ensuring that all stakeholder interests and concerns are properly addressed in the planning and conduct of the study.** Since they determine the type of data required, how the data will be analyzed, and how the results will be published, **researchers bear the lead responsibility for the ethics, scientific outcome, and merit of the study.**

Interests and concerns applicable to researchers include:

- The availability of, and access to, records.
- The availability of, and access to, workers.
- Protection from undue influence from powerful constituencies and public interests.
- Initial and continuing funding.
- Known or unforeseen scientific uncertainties in the research proposal that may affect the subjects.
- IRB requirements and multiple reviews.
- Proper handling of records and samples.
- Assuring privacy and confidentiality of records.
- Approaching other stakeholders and obtaining their understanding and cooperation.
- The ability to meet projected milestones and schedules.
- The ability to publish results.



Responsibilities of researchers include that they:

- Properly plan the study.
- Assure that the worker community has full knowledge of the research.
- Provide explanation and interpretation to subjects and their physicians where necessary.
- Provide informed consent for all stages required in the research.
- Provide adequate time for subjects to consider the informed consent materials.
- Provide timely and complete personal and programmatic feedback and results of the program to stakeholders, as appropriate (e.g., only if the subject wants the information).
- Adequately inform subjects and other stakeholders regarding the studies.
- Obtain and maintain local IRB approval.
- Assure that the rights and sensitivities of the subjects are acknowledged.
- Assure that the research has scientific merit.
- Follow protocol as approved and regulatory requirements as stated.
- Be aware of special ethical considerations when conducting worker-studies.
- Obtain peer review of research and research results and implement recommendations.

## Researchers' Institution

The researcher's home institution has a vested interest in the proper planning and conduct of any worker study. In addition to the potential liability that could result from failure to adequately monitor and manage the study and protect the privacy of data of study subjects is the risk to the institution's reputation to conduct future research. A conflict that may be real or perceived in the research institution is the need to conduct research studies as a means to continue obtaining funding.

Interests and concerns applicable to researcher's institution include:

- The quality of the research and assurance that it is good science.
- That the researcher follows IRB guidelines and all federal requirements for human studies.
- That adequate funding is made available to meet all the requirements for the protection of human subjects in research.
- Protecting worker privacy.
- Maintaining productivity (and profit).
- Protecting proprietary or sensitive information.
- Potential costs and liabilities from study findings including:
  - Liabilities and obligations resulting from improper conduct of the study.
  - Obligations that might result.
  - Detrimental results.
  - Worker compensation.
  - Worker third party issues (insurance).
- The public's perception of the institution.
- Worker-subject protection and well being.



Responsibilities of a researcher's institution include that it:

- Assures that the researcher provides the worker community with full knowledge of the research.
- Fosters a culture that supports protection of human subjects in research.
- Assures IRB availability and support.
- Assures that the research proposal has scientific merit through peer review before approval and submitting it to the funding institution.
- Approves the reviewed research proposal.
- Assures academic freedom of the researcher.
- Educates researchers in the requirements for protection of human subjects and the ethical conduct of research.
- Assures that the need for research funding and the desire to perform useful research is balanced properly with the need to provide adequate protection to workers involved as research subjects.

## Institutional Review Boards

IRBs are tasked with the oversight of reviewing and protecting the interests of health study worker-subjects—from initial planning to completion of the study. When worker health studies are reviewed, the IRB should include among its membership (or as a consultant) a worker representative as well as an independent member not affiliated with any stakeholder.

Interests and concerns applicable to IRB include:

- Awareness of the unique ethical issues affecting the worker community when research of worker-studies are planned or conducted at their site.
- Adequate time and funds to conduct the IRB review.
- The ability and resources to educate stakeholders in the requirements.
- The ability to adequately protect workers involved in projects conducted by other agencies.
- The ability to fully assess similar studies being done by other agencies on the site.
- The ability to enforce regulatory expectations.
- Mechanisms for being notified of human subjects studies that have been proposed to be conducted at the site.
- That it gives the same attention to non-physical (social) risks to workers as it does to physical risks.
- Mechanisms to ensure that the researchers adhere to the approved protocol, and notify the institution of changes or adverse events.
- The authority to terminate research that does not adhere to the approved protocol.
- The assurance that the membership of the local IRB reflects all stakeholders' interests.
- An assessment and assurance of the scientific merit of the research.



Responsibilities of the IRB include that it:

- Provides workers with a description of the IRB, including its role, purpose, and process.
- Provides researchers with relevant forms and information to complete local reviews.
- Collaborate at DOE sites with the local site office to ensure that knowledge of all site projects is maintained.
- Coordinates with each researcher's IRB when a local IRB review is conducted.
- Provides a thorough review in a timely manner, providing assistance where possible.
- Reviews all local worker studies.
- Assures that IRB members have the expertise available to adequately review the study.

- Assures a properly constituted IRB throughout the life of the study.
- Reviews study protocols annually and when there are changes in the research plan.
- Provides initial and continuing reviews and re-approvals of all research studies.
- Provides reports to management as required.

## Agency Funding the Research

**Funding agencies**, like parent research institutions, have a vested interest in the planning and conduct of the study. Adequate funds must be justified and allocated. Although funding agencies may have a reasonable expectation of a useful outcome for the research, they **must also accept that the goal of research is science¾the accumulation of general knowledge.**

Interests and concerns applicable to funding agencies include that the:

- Proposed research is reviewed by an IRB approved by the funding agency.
- Research contributes to generalizable knowledge and is of scientific merit and value.
- Research is efficiently managed in a cost-effective manner.
- Researcher has adequate facilities and technical capability to perform satisfactorily.
- Researcher and institution have an understanding of the unique ethical and regulatory considerations of worker studies issues.



Responsibilities of the funding agency include that it:

- Assures that research has merit and value.
- Notifies the site of all projects proposed and funded for that site.
- Notifies local IRB of all projects proposed and funded for that site.
- Assures that the research has adequate peer review.
- Assures that adequate funding is available for the technical effort as well as the cost of providing counseling and the ethical and regulatory protection for the worker.
- Assures that adequate funding is available for local IRB review.
- Assures that human subjects work does not begin until approved by the local IRB and by each researcher's IRB, if applicable.

## Public and Community

The community has a strong interest in protecting both the interests of the workers (residents) of the community and the viability and success of the employer. If public money is used in the study, then the use of tax revenues may also be an issue. Local press and news agencies can be important allies—or foes—early in the study process by raising issues and informing the community of the purpose, risks, and benefits of a successful worker study.

Interests and concerns applicable to the public and the community include the:

- Protection of workers as members of the community.
- Appropriate use of taxpayer dollars.
- Loss of employment and tax revenue availability.



Responsibilities of the public and the community include that they:

- Provide members for IRBs.
- Be knowledgeable about issues, concerns, and appropriate regulations relating to the study.
- Be involved.

## Government (Federal, State, and Local)

One or more government agencies may hold regulatory and enforcement authority over the conduct of studies involving workers. Often, government agencies are also the source of all or part of the funding for worker studies and may be in conflict with privacy and confidentiality expectations.

Interests and concerns applicable to government agencies include that the:

- Human subject research is conducted ethically and in accordance with applicable regulations.
- Study is conducted in accordance with the laws applicable to workers under their jurisdiction.

Responsibilities of government agencies include that they:

- Assure compliance and promulgate appropriate regulations.
- Determine and establish primacy of responsibility should conflict occur (e.g., ownership of records).



- Assure adequate funding in worker study contracts, grants, and financial plans to adequately implement human subjects protection during the study.