



PNNL Institutional Review Board Human Subjects Research Program

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Human Subjects Research Defined

Human Subject Regulations and Battelle Policy

Federal regulations for conducting human subjects research, while very specific in some areas, are purposefully written to provide a certain amount of discretion to IRBs in the management of their human subjects programs. PNNL takes a very conservative approach to the protection of humans in research. For instance, to prevent any perceived or actual coercion, our corporate (Battelle) policy forbids the use of company employees or their families without the Director's approval and then only under "minimal risk" conditions. As another example, all subjects who participate in research are provided with a copy of [The Human Subjects Bill of Rights](#) ([PDF](#)).



Gathering Oral Histories from Local Native Americans

To meet the requirements of federal, state and corporate policies, all research involving human subjects must be reviewed by the IRB, whether PNNL has the lead, is subcontracting or collaborating with another institution. IRBs often coordinate reviews to minimize duplication of efforts, but each is responsible for maintaining compliance with its institutional policies and procedures which at PNNL include documentation of scientific peer review and completion of human subject training by all primary project staff, as determined by the principal investigator.

Basic Ethical Principles

PNNL researchers and the IRB are guided by the ethical principles propounded in the [Belmont Report](#) of the National Commission for the Protection of Human Subjects (1979). The basic principles of the Belmont Report are:

- **Respect for Persons:** Provide autonomy through informed consent and protect individuals with diminished autonomy.
- **Beneficence:** (1) Do no harm, (2) maximize possible benefits and minimize possible harms.
- **Justice:** Equitable selection of subjects. Fairness in the distribution of

burdens (risks) and the benefits of research (results benefit the community being studied).

Respect for Persons (Autonomy)

The principle of respect requires that researchers obtain the informed consent of the subjects they solicit to participate in research. The process of informed consent is the "cornerstone" for protection of human subjects. To respect subject autonomy, the consent process should include a complete description of the research, including the anticipated risks and benefits, and must describe the subject's participation in clear and simple terms. Subjects must be given explicit assurances regarding the voluntary nature of their participation in terms that are easy to understand and do not coerce or place them under duress.



Researchers are required to spell out any foreseeable physical, psychological, economic and social risks which participation in the experiment might bring to the subject immediately or in the future and are responsible for confirming with the subject that they fully understand the requirements of their participation in the research.

In addition, respect means honoring the privacy of individuals and maintaining their confidentiality. Respect for minors and mentally disabled persons requires taking extra precautions to protect those individuals who are immature or incapacitated, perhaps even to the extent of excluding them from participation in certain research.

Beneficence

The principle of beneficence requires that researchers minimize the probable risks of harm to subjects and maximize the potential for benefit to the individual subject, to the subjects "community", or to society in the importance of the scientific knowledge that may be gained from the research. Before research is undertaken, a determination should be made that the risks to subjects are reasonable in relationship to the potential benefit that may be gained.

Justice

The principle of justice requires that the selection of human subjects be fair and equitable and that the risks and benefits of research be distributed among subjects in a fair and equitable manner. Particular concern should be given to subjects whose personal status or condition (e.g., children, prisoners, employees, patients, impoverished persons) places them in a vulnerable or dependent status. Researchers should be aware of the fact that circumstances sometimes make the inclusion or exclusion of these particularly vulnerable populations unfair.

Researchers should select subjects based on those factors that most effectively and soundly address the research problem and should not select subjects based simply on ease of availability. They must also be mindful of

the fact that supervisors using subordinates for research risk the appearance of soliciting cooperation with unfair pressure or coercion.

Human Subject Definitions

The Common Rule defines **research** as "... a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable (scientific) knowledge (that is generally publishable)." In the Belmont Report the term research designates "an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge." Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.

A **human subject** is currently defined as: "a living individual about whom an investigator obtains (1) data through intervention or interaction or (2) identifiable private information." (Advancing techniques in genetic research have many IRBs rethinking the use of the word "living.")

Intervention includes both "physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes."

Interaction includes "communication or interpersonal contact between investigator and subject."

Private information includes "information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual that the individual can reasonably expect will not be made public" (for example, a medical record).

Minimal Risk means "that the probability and magnitude of harm or discomfort anticipated in research are not greater in and of themselves than those ordinarily encountered in daily life or in the performance of routine physical or psychological examinations or tests".

A more comprehensive list of definitions may be found in [SBMS](#).



Evaluating human exposure to volatile organic compounds in residential water

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