

Washington State Institutional Board

REVIEW CONSIDERATIONS

The Washington State Institutional Board's primary function is to protect the rights and welfare of individuals who are involved in research in its jurisdiction. The Board must determine that:

- the proposed project design and methods are adequate and appropriate in the light of stated project purposes;
- that the rights and welfare of research participants are adequately protected;
- that participants are fully informed and provide consent voluntarily, and
- that risks to participants are minimized, are not unreasonable, and are outweighed by potential benefits to them or by the knowledge to be gained.

The WSIRB is guided by federal regulations, the *Belmont Report*, institutional policies, and applicable state laws and regulations. The *Washington State Agency Policy on Protection of Human Research Subjects* is based on federal regulations for the protection of human subjects (45 CFR 46), but like the Board, may be more restrictive. For example, some research which the federal regulations consider exempt from review *may be* subject to at least expedited review under the *Policy*.

Human subjects review also includes an assessment of local laws and regulations which may apply to a research activity. In Washington, such laws include mandatory reporting of abuse of children and dependent adults; reporting of notifiable conditions to state and local health authorities; confidentiality of HIV and STD diagnosis and treatment; access to confidential health care information; and use and disclosure of identifiable DSHS or DOH records, among others. Links to pertinent laws, codes and regulations are included in this Handbook for easy reference.

Research applications reviewed by the Washington State Institutional Board encompass a wide range of scientific and social inquiry. While no individual has expertise in all fields, Board members are chosen to ensure that as many areas of inquiry as possible are represented. The Executive Secretary and Associate Executive Secretary are available to provide consultation during the review process. Board members are encouraged to raise questions and discuss issues with Review Section staff who will provide guidance, resource materials, and referral to other sources of information and expertise.

The following areas should be carefully considered during Board deliberations:

Scientific Merit

Human subjects review begins with an assessment of the overall scientific merit and the logical and technical soundness of the research. The research application should discuss the relevant literature or describe the context in which the study will occur to provide an adequate conceptual framework. The objectives, research questions and/or hypotheses of the study should be clearly stated, and the proposed methods and study

instruments should produce data relevant to the objectives. Plans for data analysis should be well-defined and likely to produce results related to the study purposes, objectives and hypotheses. The researcher should have appropriate qualifications to conduct the project, or, if the researcher is a graduate student, adequate supervision by qualified faculty.

Study Population

Research proposals should clearly define who will be enrolled as participants in the research and explain why these subjects will be selected. Justification for inclusion and exclusion criteria should be reviewed carefully to verify that it is equitable and appropriate for study objectives. Classes of subjects should not be systematically included or excluded for arbitrary reasons. Reviewers should consider whether participants will share the benefits of the research (to individuals, the class or subjects, or society in general) in proportion to the burdens imposed by the research. If vulnerable populations are included, reviewers should consider whether the research could be done with a non-vulnerable population or whether additional safeguards are necessary to protect vulnerable subjects.

Subject Recruitment

Reviewers should examine the procedures for identifying, contacting and recruiting potential subjects. Generally, researchers should not make first contact with potential subjects. If the researcher proposes to identify and sample the study population from confidential state agency records, contact must first be made by agency employees. Sampled individuals must be provided, at a minimum, the option of refusing further contact regarding the research. Recruitment materials should provide information in language that the intended population can readily understand. Recruitment procedures should be free of undue influence or coercion.

Informed Consent

The informed consent process must provide complete information about the study

- in a manner that prospective subjects can comprehend, and
- in an environment that ensures voluntary participation.

Reviewers should consider the appropriateness of the individual(s) who will request consent, as well as the location and timing of the consent process. Researchers must provide complete information about the proposed research and what the potential subjects would be asked to do if they participate. Consent/assent procedures must also be conducted in an environment and manner that is free of coercion or undue influence. Consent/assent documents must contain all elements required under the federal regulations, and be written in reading levels and languages appropriate for the intended study population(s).

Research that will include vulnerable groups (e.g., pregnant women, fetuses, children, decisionally impaired, institutionalized, prisoners, socially or economically disadvantaged) merits special consideration. Reviewers should evaluate whether potential subjects would be capable of fully understanding the research and providing their own consent for participation. It is important to evaluate the potential for undue influence in the consent process. The Board must ensure that there are adequate

safeguards in place to protect the interests of vulnerable subjects, e.g., a consent witness or subject advocate. Assent to participate in research generally is required from persons who are decisionally impaired and/or legally incompetent or less than 18 years of age. In addition, parental or guardian permission generally must be obtained to include these vulnerable subjects in the research.

The Board may approve waivers or alterations of consent, assent, and/or waiver of parental or guardian permission provided the requirements in 45 CFR 46 have been met.

Confidentiality

Board members should carefully consider possible risks to the confidentiality of subject information in all phases of the proposed research: sampling, recruitment, consent procedures, proposed methods and setting for data collection, etc. The Board may require alterations in the study to minimize confidentiality risks. Some research may pose special confidentiality concerns, e.g., plans to collect sensitive information regarding the individual's own behavior or experiences, genetic samples, or information about illegal activities, to name a few.

Benefits and Risks

A fundamental task in the Board's review of proposals is to balance the anticipated benefits and risks of the research. Benefits accruing from research may include direct, personal benefits to the participants, such as the provision of a new procedure or drug, or the opportunity to obtain services that are only available through participating in the research. Benefits also include general societal benefits in the form of new scientific or applied knowledge.

Risk is defined as any research procedure that potentially may harm the research participant -- psychologically, physically, socially, economically, legally, or otherwise. Risks may range from physical injury from biomedical or pharmaceutical research, to mere inconvenience from participation in survey research. When assessing risks inherent in a proposal, reviewers should consider both the magnitude and probability of the harm occurring. If the balance between risks and benefits is unfavorable, the Board will require the researcher to develop plans for reducing risks and/or increasing benefits.

Review Disposition

Assuming all regulatory requirements have been met, the Board makes a decision on review disposition by balancing the risks to subjects in relation to anticipated benefits to the subjects and/or society. If the risks are outweighed by the anticipated benefits, the proposal may be approved, or conditionally approved subject to clarifications and/or revisions in procedures.

If insufficient information exists for the Board to clearly determine the risks and/or anticipated benefits of the research, or if the Board cannot based on an assumption that conditions for approval are met, a decision may be deferred until additional information is obtained and/or issues resolved in a revised research application.

If risks clearly outweigh anticipated benefits, and it is not possible to increase benefits or reduce risks, the proposal may be disapproved. The Board does not disapprove a proposal until the researcher has been given an opportunity to address issues and concerns raised by the Board, including the opportunity to attend a WSIRB meeting, OR attempts to negotiate required revisions with the researcher are fruitless.