

# Chapter 388-04 WAC

## PROTECTION OF HUMAN RESEARCH SUBJECTS

(Formerly chapter 388-10 WAC)

### WAC

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**WAC 388-04-010 Purpose.** The purpose of this chapter shall be to establish rules implementing the department's policy for the protection of departmental wards, clients, and employees who serve as human subjects in research and related activities. These rules do not supersede or limit the applicability of other state and federal laws and regulations. For example, see Title 45, Part 46 of the Code of Federal Regulations.

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**WAC 388-04-020 Definitions.** (1) "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of these rules, whether or not they are supported or conducted under this label.

(2) "Related activities" means demonstration, service, development, and other projects that contain a research component.

(3) "Human subject" means a person about whom an investigator (whether professional or student) conducting research obtains data (a) through intervention or interaction with the person, (b) through observation of the person's behavior, or (c) from personal records and other private information sources.

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**WAC 388-04-030 Statement of policy.** (1) No service unit or administrative unit within the department's jurisdiction shall allow, or shall participate in, the conduct of research and related activities unless the plans or protocols for such activities have been reviewed and approved by the department of social and health services human research review board or have been specifically exempted from this review requirement by published departmental guidelines.

(2) It is the intent of the department's human subjects protection policy that review of research and related activities by the review board determine that the rights and welfare of clients, wards, and employees are adequately protected; that risks to individuals are minimized, are not unreasonable and are outweighed by the potential benefits to them or by the

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knowledge to be gained; and that the proposed project design and methods are adequate and appropriate in the light of stated project purposes.

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**WAC 388-04-040 Implementation.** (1) The department shall maintain a human research review board which shall have primary responsibility for the ethical and technical review of the use of human subjects in research and related projects conducted within the department's jurisdiction. Unfavorable review dispositions by this review board, including disapproval of proposed research, research restrictions, or special approval conditions, cannot, by federal regulation (45 C.F.R. 46.112) be removed except by the review board. Favorable review decisions by the board shall be subject to review and concurrence by appropriate departmental officials.

(2) To assure continued protection of human subjects in on-going research at the activity site, departmental service units involved in a significant number of research and related activities shall establish their own research oversight committees. These local committees shall function as extensions of the human research review board. They shall be responsible for providing ethical and procedural oversight in accordance with the review board's directions.

(3) Review of proposals requiring professional competencies beyond those represented on the human research review board shall require prior and written review consultation with at least four research experts who are competent to judge the scientific merit, benefits, and risks of the proposed research.

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**WAC 388-04-050 General applicability.** The department's human research review rules shall apply to all organizational units of the department. They shall apply to all research and related activities that involve departmental clients, wards, or employees as human subjects or that require disclosure of their personal records, regardless of funding source, and regardless of whether the research is conducted by a departmental employee or by a nondepartmental investigator. The rules shall apply to all research and related activities subcontracted by the department under state and federal grants and contracts to nondepartmental organizations and individuals, regardless of whether the research or related activity involves departmental clients or a nondepartmental subject population.

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[WSR 99-15-021, recodified as § 388-04-050, filed 7/12/99, effective 7/12/99. Statutory Authority: RCW 43.20A.550. WSR 81-17-022 (Order 1687), § 388-10-050, filed 8/12/81.]

**WAC 388-04-060 Documentation of research proposals and review dispositions.** (1) All research and related activity proposals subject to review under WAC 388-10-050 shall be submitted in writing and such proposals shall conform to the format and content guidelines published by the department.

(2) The director of the departmental unit responsible for human research review policy administration shall document in writing all review dispositions affecting research and related activity proposals submitted to the department. In the case of unfavorable dispositions, such documentation shall contain a statement of the reasons for the negative disposition.

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**WAC 388-04-070 Human research review guidelines.** (1) The department shall develop and publish a comprehensive set of procedural guidelines for the protection of human research subjects within its jurisdiction. These guidelines shall be at least as restrictive as the minimum requirements set forth in Title 45, Part 46 of the Code of Federal Regulations, but may be more restrictive if necessary to satisfy the protective purposes of the department's human subjects protection policy.

(2) The published guidelines shall speak at least to the following topics:

- (a) Applicability;
- (b) Responsibility for policy and rule implementation;
- (c) Basic definitions;
- (d) Proposal format and content;
- (e) Review and certification requirements;
- (f) Activities exempt from review requirements;
- (g) Approval and disapproval authority; appeals;
- (h) Qualification requirements for investigators;
- (i) Review board composition and functions;
- (j) Review of ongoing research projects;
- (k) Informed consent requirements;
- (l) Disclosure of personal records for research purposes;
- (m) Publication conditions;
- (n) Provisions for adapting guidelines to the changing requirements of state and federal laws and regulations.

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