

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.

[WSR 99-15-021, recodified as § 388-04-070, filed 7/12/99, effective 7/12/99. Statutory Authority: RCW 43.20A.550. WSR 81-17-022 (Order 1687), § 388-10-070, filed 8/12/81.]