

POLICY

Group Health encourages research whose purposes, objectives, and outcomes may directly benefit the delivery of health care at Group Health and society in general.

Group Health conducts scientific studies and research relating to prevention, cure, and treatment of illness and injury, and disseminates research results in the public domain.

Group Health provides legally required mechanisms for the review, approval, management, funding, and monitoring of research at Group Health and for protecting the rights and welfare of research subjects.

All research conducted at Group Health shall be conducted in accordance with all relevant Group Health policies and applicable laws and regulations.

All research to be conducted in Group Health facilities and/or to use Group Health information, information systems, or other resources must be submitted to the Center for Health Studies for approval by the appropriate review committee(s) prior to initiation.

Research	Procedures for: F-05-001
	Adopted: 10/25/78
	Revised: 4/8/03

PROCEDURES

Implementing Policy F-05-001

Note: These procedures provide additional information related to Policy F-05-001, but are separate and distinct from that policy. The authorized Vice President retains discretion in implementing these procedures and can change them at any time, with or without notice.

Explanation:

One of the original purposes for which Group Health was incorporated, as stated in the Agreement of Association of the Cooperative, is to conduct scientific studies and research relating to prevention, cure, and treatment of illness and injury, and to

disseminate research results in the public domain. Group Health's defined population, its health information systems, and its mission to transform health care provide opportunities for pioneering contributions to generalizable research knowledge, particularly in the areas of health promotion, health services, epidemiologic, behavioral, and clinical research. Therefore, Group Health shall encourage, identify, and conduct research by investigators from various Group Health departments, including the Center for Health Studies, and in collaboration with appropriately qualified external investigators, research organizations, and funding sources. This policy and procedure for implementation support Board Policy 500-305.

Research Defined

Research is a systematic investigation designed to develop or contribute to generalizable knowledge. In the context of this policy, research requires a design specifically aimed at ensuring the applicability and potential replicability of the results in settings external to Group Health. Research is usually signified by an intent to publish findings externally in scientific or technical literature (i.e., in recognized peer-reviewed publications relating to the scientific disciplines or to clinical or administrative practice).

Though the initial methods and data sources of health evaluation studies and research may be identical, or nearly so, the ultimate purpose, and hence, the ultimate design details, usually can serve to distinguish the two. Research is designed principally to contribute to public domain knowledge whereas health evaluation studies are primarily conducted for the internal purposes of Group Health.

Research Committee

The Research Committee recommends approval of research after determining that the research question and problem significance are appropriate; the research design is adequate; and the budget, facilities, and personnel are adequate, given the research design. Research Committee membership includes individuals who have the technical expertise to assess the scientific methods of the research. The Research Committee includes scientists, physicians, representatives from appropriate departments within Group Health administration, and Group Health consumer members. Generally, a consumer member serves as the committee chair.

Human Subjects Review Committee

The Human Subjects Review Committee, as Group Health's institutional review board, protects the rights and welfare of research participants. It has authority to review, approve, require modification, or disapprove all research activities involving human subjects in accordance with Group Health's research guidelines and all applicable governmental regulations for such boards. The Human Subjects Review Committee also reviews the clinical use of investigational drugs and devices that have not been approved by the Food and Drug Administration.

The President/Chief Executive Officer's designee consults broadly within the health care community for recommendations of persons who represent diverse areas of expertise to serve on this Committee. The Human Subjects Review Committee includes scientists, physicians, other health care providers, and Group Health consumer members. It may also include community members. One of the management representatives is from the Group Health Legal Department and one is from the Center for Health Studies. Generally, a Group Health consumer serves as Committee Chair.

The Research Advisory Board

The Research Advisory Board periodically, at minimum annually, reviews research activities of Center for Health Studies, research conducted by other departments of Group Health and by Group Health Permanente staff, and the health of the Center for Health Studies as a public domain, grant-funded research organization.

The Board assesses the following issues:

- a. The quality, innovation and relevance of Group Health research in enhancing quality of care and consumer value within Group Health and nationally.
- b. Strategic opportunities for future research in the Group Health population.
- c. The strength of the Center for Health Studies in terms of its abilities to realize its mission and its ability to remain competitive for external grant funds.

The Research Advisory Board, appointed by and reporting to the Group Health President/Chief Executive Officer, includes the Group Health President/Chief Executive Officer or designee, the Medical Director of Group Health Permanente or designee, a representative of the Board of Trustees, a consumer representative, a representative of the Group Health Permanente medical staff, the President of the Group Health Community Foundation, and two or more nationally prominent researchers selected from major research institutions within and outside Seattle. The Center for Health Studies staffs the Research Advisory Board.

Guidelines:

Research at Group Health or by Group Health employees is conducted in accordance with all applicable state and federal law. Individually identifiable health information is not used for research purposes unless:

- Group Health (or the appropriate entity) obtains the individual authorization of each research subject, or
- An institutional review board, such as the Human Subjects Review Committee, waives the need to obtain individual authorization in accordance with law.

Researchers working at Group Health safeguard the privacy of research subjects by following the procedures stipulated in the research proposal approved through the procedures described above and by contractual agreements as needed.

All research to be conducted at Group Health or by Group Health employees must be submitted to the Center for Health Studies for review by the Research Committee and/or Human Subjects Review Committee as required by guidelines for each committee and in accordance with applicable law. Generally, research proposals are reviewed first by Research Committee and, if approved, then reviewed by the Human Subjects Review Committee.

The Group Health management representatives to the Research Committee and the Human Subjects Review Committee maintain written guidelines for the review process of both committees, each of which has different requirements and focus.

Each committee may review research proposals as a convened group or using an expedited process, depending on factors such as the degree of risk to subjects, impact on Group Health, and whether Group Health enrollees will be research subjects. The Research Committee chair, or his/her designee, may waive Research Committee review for projects that have little or no impact on Group Health staff, facilities, or information systems.

To avoid duplicative reviews by multiple institutions, Group Health may accept the approval of research proposals by other institutional review boards in lieu of Human Subjects Review Committee review in accordance with Human Subjects Review Committee guidelines and all applicable state and federal law.

Applicability:

This policy applies to all Group Health members/patients and all individuals authorized to access, use and disclose Group Health Cooperative information and information systems.

Scope:

This policy applies to research that is conducted in Group Health facilities and/or uses Group Health information, information systems, or other resources.

Responsibilities:

The Group Health President/Chief Executive Officer or his/her designee establishes the Research Committee, the Human Subjects Review Committee, and the Research Advisory Board and designates one or more Group Health management representatives to provide administrative support for each of these bodies.

The Research Advisory Board assesses research conducted by the Center for Health Studies and other Group Health departments, strategic opportunities for research, and the ability of Center for Health Studies to realize its mission.

The Center for Health Studies Director plans and directs research with Group Health. He provides oversight of the administration, funding, and performance of approved research conducted by Center for Health Studies investigators and staff.

The Research Committee recommends approval of research that is appropriate for conduct at Group Health.

The Human Subjects Review Committee, as Group Health's institutional review board, protects the rights and welfare of research participants.

Definitions:

- **Research:** a systematic investigation designed to develop or contribute to generalizable knowledge.

References:

Standards:

- National Committee for Quality Assurance
- Joint Commission for Accreditation of Healthcare Organizations

Related Group Health Policies and Documents:

- Accounting of Disclosures of Patient-identifiable Health Information, F-06-404
- Center for Health Studies departmental policies and procedures
- Confidentiality of Patient-identifiable Health Information, F-08-002
- Creation, Use, and Disclosure of De-identified Health Information, F-08-402
- Group Health Notice of Privacy Practices
- Individual Confidentiality and Security Accountability, F-08-201
- Regular Board Meeting minutes 10/25/78, 05/25/83.
- Use and Disclosure of Patient-identifiable Health Information, F-08-401
- Violations of Confidentiality and Security Policies and Procedures, F-08-202

Legislation:

- Healthcare Insurance Portability and Accountability Act of 1996 §164.530
- Protection of Human Subjects, Title 45 CFR 46
- Revised Code of Washington, 70.02