

Description of Research Review Process at Group Health

Group Health Cooperative encourages research on topics of importance in public health, epidemiology, disease prevention, and health services delivery. Because there are many worthwhile proposals that utilize Group Health as a research site, there is an administrative approval process to ensure that this research has well-designed scientific methods; has potential scientific and/or public health value which merits the use of Group Health resources; has adequate financial support; and is feasible, given the Group Health care delivery system.

Research review at Group Health consists of an initial feasibility review, a design and impact review, and a human subjects review (IRB review), each described below. The goal of this review is to facilitate good research through a process that is thorough, yet flexible.

Initial Feasibility Review

If your project will require Group Health and/or Center for Health Studies (CHS) staff to obtain data from Group Health databases, contact subjects, review medical records, or perform other tasks, including clinical interventions, please call Cheryl Wiese at (206) 442-4041, to discuss whether and how your project can be done at Group Health. Since not all proposed projects are appropriate for Group Health, you may be asked to submit a brief description of proposed research before you complete a Group Health research application. The purpose of this discussion and feasibility review is to assist you in designing your project so that it works well at Group Health. In addition, development staff will be able to guide your project through this initial feasibility review and if approved, help ensure that it has a budget adequate to cover the costs of doing the necessary work at Group Health.

Final approval of a research project at Group Health is based on a design and impact review, and an IRB review. To apply for this approval you will need to complete the attached Research and Human Subjects Review Application. This application is used for both the design and impact review and the IRB review. Instructions for completing this application are included in the application itself. Submission instructions are on the next page.

Design and Impact Review

The design and impact review is conducted by Group Health Cooperative's Research Committee. Please call Barbara Young at (206) 287-2919 to discuss whether your project needs to be reviewed by the convened Research Committee. The purpose of the Research Committee review is to assess the scientific design of the research, the adequacy of the budget and resources for accomplishing the project, and the potential impact of research on Group Health's care delivery system. Based on this assessment, the Committee makes a recommendation to approve, modify, defer, or disapprove the application. The Research Committee generally meets monthly in the evening (see schedule on next page), and investigators are asked to come to the meeting for about a half-hour to answer questions about their proposal. Students and fellows are asked to bring one of their teachers, mentors, or dissertation committee members with them to the Research Committee to help them respond to questions about the research plan.

IRB Review

The institutional review board (IRB) at Group Health is the Human Subjects Review Committee, which also meets monthly, usually on the third Tuesday. This review usually does not require investigator attendance. The purpose of this review is to determine whether research benefits outweigh risks, whether risks to study subjects are minimized, and whether those invited to participate in research are given adequate information and an opportunity to decide if they wish to participate.

Group Health has cooperative agreements with several institutions, which gives Group Health the option of accepting the institutional review board (IRB) review done by one of these institutions (such as the University of Washington, Fred Hutchinson Cancer Research Center, Virginia Mason Medical Center, etc.) Accepting this review is not automatic and these cooperative agreements do not mean that Group Health administrative approval (including feasibility review and design and impact review) is waived.

Some research projects may be eligible for HSRC expedited review or may be considered exempt from review. The research application process for such projects is the same. Please notice that most research based on medical record reviews in Washington State must be reviewed by an IRB and that exemption from IRB review may not be determined by the investigator. Please contact Barbara Young for a certification of exemption.