



Clarification of Ethical Review Requirements for Studies Involving Quality Assurance/Improvement, Program Evaluation, Operational Review and Product Evaluation

Approved by FH Executive Committee: 2005 September 27

1. Studies Requiring Ethical Review

For the purposes of interpretation of the FHA policy "The Ethical Conduct Of Research And Other Studies Involving Human Subjects" research studies involving human subjects which require ethical review are defined as:

- any systematic investigation (including pilot studies, exploratory studies, and academic course work assignments¹) designed to contribute to generalizable knowledge. Generalizable knowledge consists of facts, theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference.
- Systematic investigation may, for example, include comparative studies that examine materials or practices in which at least one comparator represents an unknown or untested variable [e.g. randomized controlled trials], analysis of secondary qualitative or quantitative data to establish generalizable trends or principles, epidemiological studies, behavioural research using qualitative methods of analysis, etc.

*Note that ethics approval must be obtained BEFORE a study begins; ethical approval will not be granted after the fact.

2. Studies Not Requiring Ethical Review

The following types of studies generally do not require ethical review as these studies are considered to be a required component of FH's mandate to deliver services and programs and are designed to meet the specific requirements of FH only:

- evaluation of programs or practices within the mandate of FH that are conducted in order to assess the performance of the program/practice,
- evaluation of employees or students as within the mandate of FH,
- quality assurance/continuous improvement studies,
- operational/performance reviews,
- product evaluation of approved products specific to FH.

2.1 Exceptions: Studies That May Require Ethical Review

- ❖ If the types of studies described above, which are focused primarily on evaluation/assessment for internal FH purposes also include an element of research [i.e. intent to generalize to a wider population], the FH Research Ethics Board should be consulted in order to determine if ethical review is required.
- ❖ In addition, it is the responsibility of FH staff to meet the terms and conditions of any publisher or conference host should their study be submitted for publication or presentation. *These terms and conditions may require evidence of ethical review and approval.* **Because ethics approval will not be provided after a study has commenced,** it is the responsibility of FH staff to become familiar with the ethics requirements of publications/conference hosts if there is any intent to publish/present in the future.

¹ FH staff who are required to carry out a research study as a requirement of their academic program of study must submit their research study for ethical review to the Fraser Health Research Ethics Board IF the research is being conducted within FH.