



Is my project research or quality assurance?

Some projects are not easily characterized as quality assurance or research simply due to the nature of the project design and outcome under consideration. The following guideline is designed to aid in determining the need for research ethics review. Remember: research is defined as a class of activities designed to develop or contribute to generalizable knowledge. Generalizable knowledge consists of 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.

Apply the checklist below to help characterize your project. While there is no real way to quantify the answer to your research or quality assurance question, if the majority of your answers are "yes" under RESEARCH, then it is likely you are conducting a research project and should work with the Research Initiative to submit your project for ethics review. If the majority of your answers are "yes" under QUALITY ASSURANCE, then you need to determine your design and analysis, but probably won't need an ethics review board to review your project for ethical or safety issues and design. Please note however, if you are interested in publishing the results of your quality assurance project, it will require ethics review PRIOR to project initiation. The EHS Prehospital Research Initiative can help you with this. The QEII Research Ethics Board requires any submissions involving EHS to be reviewed by the Prehospital Research Initiative prior to submission to its ethics committee.

If you are still unsure and would like a more formal opinion from the Prehospital Research Initiative, please submit maximum one page summary of the project to the research office with your contact information.

Yes/No	RESEARCH	Yes/No	QUALITY ASSURANCE
	The goal of the project is to test an hypothesis		The goal of the project is to improve service delivery
	You are using scientific methods (e.g., controls, blinding, randomization) and the outcome of the project is uncertain		The project has a reasonable expectation of success
	The planned procedures deviate from normal clinical care		There is no change in normal clinical care
	You expect to draw generalizable conclusions		The findings will be used to improve patient service delivery only
	You expect to publish your findings in a scientific journal		Publication is not intended

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The following criteria is contained in the Tricouncil Policy Statement and provides further information as to what should be reviewed by an ethics committee and hence the Prehospital Research Initiative.

¹ <http://www.cdha.nshealth.ca/research/researchEthics/frequentlyAskedQuestions.html>

Scope of Research Requiring Ethics Review

The following which is adapted from the University of Alberta, *General Faculty Council Policy Manual* indicates the range of research projects or instances that should be reviewed by the REB; whether the research is funded or not;

- Whether the funding is internal or external;
- Whether the subjects are from inside or outside the institution;
- Whether the subjects are paid or unpaid;
- Whether the research is conducted inside or outside Canada;
- Whether the research is conducted inside or outside the institution;
- Whether the research is conducted by staff or by students;
- Whether the research is conducted in person or remotely (e.g., by mail, electronic mail, fax or telephone);
- Whether the information is collected directly from subjects or from existing records not in the public domain;
- Whether the research is to be published or not;
- Whether the focus of the research is the subject;
- Whether the research is observational, experimental, correlational or descriptive;
- Whether a similar project has been approved elsewhere or not;
- Whether the research is a pilot study or a fully developed project;
- Whether the research is to acquire basic or applied knowledge; and
- Whether the research is primarily for teaching or training purposes or whether the primary purpose is the acquisition of knowledge.²



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² http://www.ncehr-cnerh.org/english/code_2/apdx01.html