

Research by Students and Residents

Guidelines for Deciding Whether Studies at Kingston General Hospital Require Research Procedures

Our office, similar to other research entities throughout the country, is being increasingly asked questions as to what kinds of investigative projects qualify as research, and require adherence to research protocols and regulations. With the increase in needs for hospital administration accountability, and accountability for clinical practice, this is becoming more frequent, as the distinction between investigations for quality assurance etc. merges in a gray zone with some aspects of research. At times a project may start out as an administrative exercise, and develop into a project that might otherwise be considered research. It is hoped that this note will provide some guideline. Broadly, there are four categories that need to be defined in our hospital: pure research projects, quality assurance projects, student critical inquiry projects, and administrative projects.

➤ **Pure Research Projects:**

In general only this category, namely that of pure research projects, require strict adherence to research procedures, including the need for Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board approval, and completion of the Queen's University Data Summary and Signature Sheet (DSS) which tracks the impact of the research project on the operations of the various departments within the hospitals. Although there may be variations, these projects involve the identification of a hypothesis or a problem, and a well-reasoned methodology to investigate this. The intention would be (if the results merit this and if they are conducted with sufficient scientific rigor) to publish these in peer reviewed journals or present the data at scientific conferences. For these projects the procedures and policies are covered by Policy No. 11-150, which also includes adherence to the research provisions of the privacy legislation.

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➤ Quality Assurance Projects:

These are generally demanded by any hospital organization, for on-going accountability and oversight. Usually they are not intended for publication, and are designed specifically to assure optimum patient care within the hospital. These types of projects do not require Research Ethics Board approval, as they constitute patient care, however, a KGH/HDH/PC Research Application form must be completed online, in order to track the impact of the quality assurance project on the operations of the various departments within the hospitals, and a copy of the project must be dropped off to the Office of Research Development.

The problem that may arise with quality assurance projects, is that the results of the study may reveal important trends, inferences, etc. that maybe deemed to be of importance for further study and/or publication, either at the time of study or in the future. Under these circumstances the provisions of the procedures and policies covered by Policy No. 11-150 come into play. Before research can proceed further, or before the results can be either submitted or discussed, the research project will then have to be approved by the Research Ethics Board. Under certain circumstances the Research Ethics Board may deem the conduct study to be congruent with ethics requirements with no further changes, but the Research Ethics Board may require the researcher to return and attain the necessary requirements, such as consents, if they were lacking. This may prove difficult to provide post hoc.

For this reason, it is advisable, that every study that is undertaken should be approached from the outset with the question being asked as to whether it could turn into a research project. If the investigator believes this possibility may exist, it would be advisable to obtain the necessary consent forms and Research Ethics Board approval right from the beginning. Should this remain a strictly administrative

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project, it is covered by hospital procedure, is congruent with the privacy legislation, and requires no further action.

➤ Student Critical Inquiry Projects:

Many of the same points raised by quality assurance projects hold for critical inquiry projects. If these are going to involve either quality assurance as part of a departmental or individual physician practice, Research Ethics Board approval may not be necessary, however, a KGH/HDH/PC Research Application form must be completed online and a copy of the project must be dropped off to the Office of Research Development. Moreover many critical inquiry projects are started with the idea that these will be of sufficient depth and quality to be potentially publishable. It is important therefore to remember that all such projects should be treated as research projects, and the provisions of the procedures and policies covered by Policy No. 11-150 come into play. Students should be strongly encouraged to go through this procedure, not only for a learning process, but in order to allow for future publication.

➤ Administrative Projects:

Administration carries out numerous studies related to hospital functions, from admissions to bed statistics, operating room data and discharge data. Should these yield publishable data, the same qualifications mentioned above would apply. Although individual consent may or may not be necessary in these studies, it is important to realize that this will be determined in each case by the Research Ethics Board, and therefore if there is any question of publication, the proposal should be formulated and submitted to the Research Ethics Board and to the Office of Research Development. If Research Ethics Board approval is not required for this type of project, a KGH/HDH/PC Research Application form must be completed online

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and a copy of the project must be dropped off to the Office of Research Development.

- ❖ Please remember that *every* Research study, whether done by a student or anybody else, has to be approved through the submission of the proposal to the Research Ethics Board and completion of the DSS to capture impact of hospital operations, according to Policy No. 11-150.

- ❖ Please keep in mind that these policies regarding what types of projects require Research Ethics Board approval may change in the future. Ethics bodies of all sorts, including the Federal Tri-Council Panel on Research Ethics, are discussing the issue of which projects need REB approval and which do not. The Federal Tri-Council's *Policy Statement for Ethical Conduct of Research Involving Humans* (http://www.pre.ethics.gc.ca/policy-politique/tcps-eptc/docs/TCPS%20October%202005_E.pdf) defines what types of projects require Research Ethics Board approval. It is possible that recommendations may be altered by Federal or Provincial policy to require consent forms and Research Ethics Board approval, etc. for all such types of projects mentioned above. The Tri-Council has completed a second draft to their policy statement (<http://www.pre.ethics.gc.ca/policy-politique/docs/TCPS-Draft2-eng.pdf>).