

## *The Pharmaceutical & Therapeutics Committee*

The Kingston General Hospital/Hotel Dieu Hospital (KGH/HDH) Pharmaceuticals & Therapeutics Committee (P & T Committee) is responsible for the review of clinical drug research trials in order to ensure that:

- ❖ There is adequate pharmacologic rationale for conducting a new clinical drug research trial at KGH/HDH;
- ❖ The clinical trial drugs are prescribed, dispensed and administered in a safe and appropriate manner; and
- ❖ There is adequate information in the clinical drug research trial's protocol regarding the storage, preparation, administration, and side effects of the drugs being used in clinical drug research trial.

When researchers submit their research study to the Queen's University Health Sciences and Affiliated Teaching Hospital Research Ethics Board (REB), a copy of the submission documents is automatically forwarded to the P & T Committee by the REB if the research study is labeled a **Clinical Drug Research Trial**. There are certain sections in the REB form that need to be addressed if researchers are conducting a clinical drug research trial.

Upon receipt of the submission package, the clinical drug research trial is reviewed at the next meeting of the P & T Committee. After the clinical drug research trial is reviewed, researchers will receive written notification with one of the following responses:

- ❖ The clinical drug research trial is approved as submitted, or;
- ❖ The clinical drug research trial's approval is pending with minor modifications or clarifications (resubmission not required), or;
- ❖ The clinical drug research trial requires major modifications and must be resubmitted, or;
- ❖ The clinical drug research trial is not approved.

## *The Pharmaceutical & Therapeutics Committee*

**NOTE: The P & T Committee must approve all clinical drug research trials prior to the enrollment of subjects into the clinical drug research trial, even if the researcher has already obtained approval from the REB or other committees.**

If time is of the essence for researchers initiating their research study, it is strongly recommended that they notify the P & T Committee in advance that they have submitted their research study to the REB and would like their research study reviewed by the P & T Committee immediately at their next meeting. The P & T Committee normally reviews each submission package at their next available scheduled meeting, if time warrants, otherwise it is reviewed at the following meeting.

For more information regarding the P & T Committee, please consult the Queen's University Health Sciences and Affiliated Teaching Hospital Research Ethics Board's *Guidelines for Handling of Drugs in Clinical Studies* (<http://www.queensu.ca/ors/researchethics/REB.html>) and/or the KGH Pharmaceuticals Policy 14-100 *Clinical Drug Trials* (<http://intranet.kgh.on.ca/defaultnc.aspx?page=1&Doc.Id=540>).