Reviewer’s report

Title: Collaborative H1N1 Adjuvant Treatment (CHAT) Pilot Trial A Canadian Critical Care Trials Group Project in collaboration with the International Forum for Acute Care Trialists

Version: 1 Date: 8 December 2010

Reviewer: Gordon Doig

Reviewer’s report:

This is a very interesting collaborative project. I wish you all the best in your undertaking. Please consider and address the following minor issues:

1. Many readers remain confused between allocation concealment and blinding. In your paragraph on Study Randomization, I recommend you explicitly use the term Allocation Concealment to refer to the methods that will be used to maintain Allocation Concealment. I recommend the sentence “The site investigators, research coordinator, clinical pharmacist involved in the care of the patient and all other study personnel will remain blinded to treatment assignment.” Should be moved to the section on blinding.

2. Section on Study Randomization: Please explicitly report all stratification variables.

3. Should the larger trial never eventuate, or the larger trial is manifestly different from the pilot feasibility trial, the clinical outcomes of the pilot feasibility trial must be published. Please stipulate your commitment to publishing the clinical outcomes of this pilot feasibility trial under these circumstances.

4. Please stipulate the circumstances under which the pilot feasibility data may not be pooled with the results of the larger trial.