



FACULTY OF | UNIVERSITY OF
MEDICINE | CALGARY

March 7, 2012

Dr. Andrew Kirkpatrick
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OFFICE OF MEDICAL BIOETHICS

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Dear Dr. Kirkpatrick:

RE: Management of Occult Pneumothoraces in Mechanically Ventilated Patients - Calgary Pilot Study

Ethics ID: 18724

Your request to modify the above-named protocol has been reviewed and approved.

Please be advised that it is permissible for you to make the following modifications to your existing protocol for the above noted study, based on the information contained in your correspondence dated March 1, 2012:

1. To enroll any stable patient undergoing or about to undergo positive pressure ventilation in whom the treating clinicians believe a pneumothorax which is present is Occult, based on their diligent review of the chest radiograph.
2. The definition of "Occult" is in the best judgment of the treating clinical time at the time a decision regarding prophylactic chest drainage is first required, rather than after all the formal radiology dictated reports have been finalized.

A progress report concerning this study is required annually, from the date of the original approval (2006-03-30). The report should contain information concerning:

- (i) the number of subjects recruited;
- (ii) a description of any protocol modification;
- (iii) any unusual and/or severe complications, adverse events or unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, or complaints about the research;
- (iv) a summary of any recent literature, finding, or other relevant information, especially information about risks associated with the research;
- (v) a copy of the current informed consent form;
- (vi) the expected date of termination of this project.

Thank you for the attention, which I know you will bring to these matters.

Yours sincerely,

Glenys Godlovitch BA(Hons), LLB, PhD
Chair, Conjoint Health Research Ethics Board

GG/rm

c.c. Ms. Linda Knox
Ms. Corina Tiruta
Mr. C. Ball