

**THE 2005 MOTIONS FROM THE CANM DECLARING THE ONTARIO
GOVERNMENT AND CCO EXPERIMENTS ON CANCER PATIENTS
UNETHICAL**

Thursday, May 12, 2005

17:00 – 18:00

***Pacific Ballroom, The Fairmont Hotel Vancouver
Vancouver, B.C.***

**MINUTES OF THE ANNUAL GENERAL MEETING
CANADIAN ASSOCIATION OF NUCLEAR MEDICINE**

MOTION:

Be it resolved that:

The CSNM strongly recommends that the PET Trial sites in Ontario immediately suspend their participation in the four Ontario clinical PET trials and not participate in the upcoming registry trials until the ethical, operational and financial concerns raised by these trials are satisfactorily addressed by the provincial PET steering committee and the Ontario Ministry of Health.

CARRIED

MOTION:

Be it resolved that:

The CSNM strongly urges the Ontario Ministry of Health to immediately and adequately fund clinical PET in the province using the CMS guidelines as an interim template until such time that provincial guidelines for its use can be put in place.

CARRIED with two abstentions

MOTION:

Be it resolved that:

The CSNM recognizes that the scientific evidence available to the medical community is such that these trials cannot be regarded as ethical because they impede medical access to patients for whom the technology has been proven to be of value. The CSNM recommends an external review by a nationally recognized institute in health care and medical ethics be conducted to resolve this issue.

CARRIED with one abstention

**COMMENTS I MADE TO ANOTHER PHYSICIAN ABOUT THESE
MOTIONS:**

The following is part of a letter I have sent to another Government body.

“Again I emphasize that this is not the typical response you see to various researchers who might disagree, even passionately, about the literature. This is a respected body of experts in nuclear medicine and research who have declared these trials as unethical.

1. In a course on Good Clinical Practice I recently completed from the National Institute of Health in Bethesda Maryland under the section on INFORMED CONSENT it was stated: (emphasis added)

“Informed consent in research means more than simply obtaining the signature of the potential research participant. It is a process that involves conveying accurate and relevant information about the study and its purpose; disclosing known risks, benefits, alternatives, and procedures; answering questions; and enabling the potential participant to make an informed decision about whether to participate.”

Under ELEMENTS OF CONSENT: (again emphasis added)

“The research team must DISCLOSE all relevant information to the potential participant. The information must be sufficient to allow the potential participant to decide whether to participate. It is generally accepted that the potential participant must be given the following information: the purpose of the study; nature of the procedure; reasonable alternatives to the proposed intervention; and risks, benefits, and uncertainties of each possible intervention.”

You will recall that to the best of my knowledge those in the lung cancer trial are not informed that this is standard of care effectively in the rest of the world.

It is also a clear expectation of GCP that experimental trials should serve some scientific purpose, usually to advance knowledge of the specialty or of uses of technology. Since the PSC Lung and Breast PET trials very

clearly do not do this, and again this violates ethical principles. The lung trial is simply a blatant denial of the evidence, since for the rest of the scientific world the role of PET in lung cancer is virtually the 'poster child' for demonstrating the role of PET in cancer. For the Breast trial, as I will demonstrate, this is a blatant misrepresentation of the capabilities of the technology and will add almost nothing to the world body of knowledge. Further it will not assist the MOH in determining the role of PET in breast cancer since the major endpoint of the trial is designed to show where PET IS NOT USEFUL IN THE APPLICATION THEY ARE TESTING. This has been repeatedly pointed out to the MOH by Dr. XXXX and others. Any authoritative medical textbook written before the trials were published made it clear that PET was not useful for the purpose the PSC was proposing."

I would be more than happy to make more of this letter available to you if this would be helpful.

Dave