



Council of Academic Hospitals of Ontario
Leadership and discovery for tomorrow

Submission to

**The Legislative Assembly of Ontario
Standing Committee on Social Policy**

Regarding

Personal Health Information Protection Act, 2004

28 August 2008

CHECK AGAINST DELIVERY

Good morning. My name is Mary Catherine Lindberg, and I am the Executive Director of the Council of Academic Hospitals of Ontario. I would like to introduce my colleague Mary Jane Dykeman, a lawyer specializing in advice to academic hospitals, including on privacy and research matters. In particular, Mary Jane has provided us with considerable advice related to the Personal Health Information Protection Act, 2004 (PHIPA).

The Council of Academic Hospitals of Ontario (CAHO) acts as the collective voice of Ontario's 25 academic hospitals. Ontario's academic hospitals, in full affiliation with our province's six medical and health sciences schools, have a threefold mission to Ontarians: they provide specialized and advanced care to patients from within and outside their communities, they teach future health care professionals, and they conduct the health research that leads to tomorrow's health care advances. We're the hospitals of last resort – the hospitals that provide the highly specialized acute care.

Our members are also members of the Ontario Hospital Association. We have worked closely with the OHA in our review of PHIPA, and CAHO and its member hospitals fully support the positions and recommendations set out in their submission to this committee. I understand that OHA is scheduled to present just after us today.

This morning CAHO will focus its submission on the direct impact of the PHIPA legislation on our members' unique and most significant contribution to the system: health research.

Ontario is the fourth largest health research centre in North America. Twenty-five academic hospitals and affiliated research institutes employ 10,000 researchers and generate over \$850 million annually in research activity.

Ontario's academic hospitals are home to 80% of all of Ontario's health research.

Ontario's health research enterprise is internationally renowned, with some of the world's most highly cited health researchers located within our universities and research hospitals. In this post-genome era, we are developing unprecedented insights into how the human body works and making progress on how to intervene to prevent, treat and cure disease. With chronic diseases on the rise and an increasingly aging population, this new knowledge will be needed more than ever.

Health research necessarily involves people. Clinical trials, one vital aspect of health research, are studies involving volunteer research subjects. These studies answer questions about efficacy, safety, impact on quality of life, and a host of other crucial issues.

CAHO has recently completed an extensive initiative to standardize clinical trial agreements, with the ultimate result that the academic hospital, principal investigator in the study, and the drug sponsor now have a common set of ground rules to which they agree. These agreements include the usual contractual language about insurance and other standard terms and conditions; however, they also speak specifically to the standards that must be met to protect individual privacy, as well as the confidentiality of personal health information. Our member hospitals have adopted these “CAHO principles” and present a united front to industry sponsors on ground rules around health privacy and research.

Which brings me to the impact of PHIPA on health research in Ontario.

Our primary goal in research is to promote excellence in the delivery of health care without doing harm. Clinical researchers and hospital administrators support safeguards for personal health information, to prevent its misuse. Researchers have dealt with issues of individual privacy protection and the confidentiality of personal health information for many years now in the work that they do. They recognize that the relationship between researchers and research participants (and by extension, the personal health information of these research participants) must be based on trust and respect. The challenge for legislation such as this is finding the sometimes sensitive balance between privacy concerns and the need for societal advancement in areas such as medical discovery. We need clinical trials. They save lives. They make lives better.

It is the position of CAHO that the PHIPA legislation as it is currently written does support the health research mandate of Ontario’s academic hospitals. We ask that this sensitive balance be maintained as the Standing Committee considers proposed changes to PHIPA.

We want to ensure that we maintain an environment within Ontario that ensures a health care system that is continuously improving, while being respectful and protective of the rights of the individuals whom it serves. We would be pleased to work with you to ensure that an appropriate balance is maintained.

We understand that there may be some consideration of increasing the transparency of the activities of research ethics boards, including mandatory publication of documents related to clinical trials, such as letters of approval issued by a research ethics board.

For those of you who may not be familiar with a research ethics board, research ethics boards have the responsibility of assessing the ethics of all research that is undertaken within their organization. The purpose of a research ethics board is to ensure that all research involving human subjects is carried out with the highest scientific and ethical standards, and to ensure safeguards are developed which provide the greatest protection to patients and members of the community who serve as research subjects. These are arms-length entities.

Ontario's academic hospitals are fully committed to transparency and accountability, but in this area we must offer some caution.

In the case of research ethics boards, we believe current requirements already protect patient privacy as well as provide rights to access information. These include:

1. Patients interested in participating in a research study must at the outset provide informed consent. As a result, there is an obligation to provide these individuals with full disclosure concerning the study, including potential risks and benefits. This information is provided directly by the research team, and typically, contact information for the principal investigator, as well as the research ethics board, is provided to the individual, in case they have any further questions, whether early or late in the process. In some instances, personal health information may be used or disclosed for research purposes without consent, (such as in a retrospective chart review) but only as permitted by PHIPA, where a research ethics board has turned its mind to whether it is appropriate to permit this to occur. A good example would be in the case of epidemiological or longitudinal studies (that is, studies undertaken over many years) – in such studies obtaining individual consent would be impractical (this is part of the criteria set out in PHIPA) but there is a strong public interest in supporting the research.
2. A publicly-accessible searchable web database of clinical trials already exists (at <http://clinicaltrials.gov>) to provide additional information to interested parties. This database provides information relating to over 60,000 clinical studies, across 157 countries, including the trial's purpose, who may participate and their location.

3. Research ethics boards are arm's length entities – arm's length from hospitals, researchers, and industry. There is little evidence to date to suggest that their impartiality has been undermined.
4. Section 15 of the regulations to PHIPA mandates that each research ethics board be constituted in a particular manner in order to serve the public interest. This includes having a member on the Board with expertise in privacy. In practice, research ethics boards are becoming more attuned to privacy matters, and incorporate these into their ethics review of prospective studies.

Finally, the Information and Privacy Commissioner of Ontario, as the oversight body under PHIPA, continues to have the power to investigate complaints, including those related to research, as well as to initiate investigations in her own right. This oversight should be maintained.

A robust research environment is necessarily rooted in innovation and intellectual property. Our recommendation is that we carefully weigh perceived privacy concerns against any solution that may jeopardize a necessary level of confidentiality in health research that promotes and sustains innovation and investment.

Our recommendation, therefore, is to maintain current requirements for transparency of research ethics boards, as an appropriate balance that has been struck between necessary disclosure to patients and the public, and the confidentiality required to preserve intellectual property.

We appreciate the opportunity to share our position with the Committee. We thank you for your careful consideration of the very important issue of patient confidentiality, and we would welcome the opportunity to discuss our comments further, and to answer any questions that you may have.