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# Ethical concerns in community practice research

## *Common concerns encountered by the Alberta Family Practice Research Network*

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Primary care research is important. "The ecology of medical care" assessed where people in the United States receive health care.[1,2] Of 1000 persons, 217 developed symptoms and sought medical attention. Of these, less than 1% were hospitalized in an academic medical centre. Research done in these centres does not represent common problems or concerns, and many primary care questions might not be detected.

The success of biomedical research has been, in part, due to the infrastructure supporting this research in academic and tertiary settings.[3] With increased interest in primary care research, researchers are approaching family physicians to recruit patients for their projects. While family practice research networks provide resources for primary care research, these community laboratories are inadequately funded.[3,4] Community family physicians have limited resources and expertise to deal with the many research requests that cross their desks. In Alberta, the Alberta Family Practice Research Network, an initiative of the Alberta College of Family Physicians, ensures that research projects are relevant and sensitive to community physicians.

The purpose of this paper is to describe some common concerns among family physicians assessing research projects. We believe it is important to increase awareness of the potential ethical and legal problems that can occur.

## Patient recruitment

Community physicians are often approached to assist with recruiting patients for projects. Researchers might request permission to post an advertisement or to give patients a handout describing the research project. These requests seem harmless because specific health information is not being disclosed.

## Ethical approval and research ethics boards

It is essential that a research ethics board approve projects before recruitment is undertaken. If the project does not have ethical approval, there could be risks to patients. When family physicians advertise a project in their offices, patients might think the physicians have endorsed the project. Hence, it is important to ensure projects meet certain ethical requirements. Alberta's Health Information Act (HIA) requires a family physician to ask researchers for a copy of the research approval letter before assisting with a project. In provinces that do not have such legislation, this might still be a wise step to take.

Research ethics boards review protocols to ensure that certain criteria are met and that patients' privacy and the confidentiality of their health information are safeguarded. They are guided by the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans,* which articulates a broad ethical framework. This statement can be found at **http://www.ncehr-cnerh.org/english/code_2/**. In most instances, ethical approval by a research ethics board is adequate. The ethics board, however, might not fully understand family practice, the unique doctor-patient relationship, and the effects that research can have on family physicians.

In some cases, researchers might request, and ethics boards might grant, a waiver of the need for consent for the release of health information (such as patient contact numbers). Physicians still have the right, however, to demand consent for release of information in these situations. Even though an ethics board could have reviewed a project it is still important that community physicians consider the power of the doctor-patient relationship to avoid conflicts of interest or misunderstandings.[5] When recruiting patients for a research project, the family physician's role as patient advocate sometimes conflicts with the research role; the family physician might be a "double agent." This role conflict

*This article is based on a similar paper published on the Alberta College of Family Physicians website (***www.acfp.ca***) and portions are reprinted with permission.*

has been described when researchers recruit patients into their own projects.[6-8]

## Common dilemmas

There might be situations in which physicians are uncomfortable with their role in research for ethical reasons. For example, physicians might be uncomfortable with the way patients are approached to participate in projects. The researchers might have asked the physicians to provide patients' contact information so that the researchers could contact patients directly to obtain consent. Many researchers prefer this approach because they think enrolment will be higher than if physicians simply hand out information to patients. Some researchers might suggest imposing a higher standard of consent. They could develop consent forms for release of contact information to reinforce that participation is voluntary from the community physician's perspective.

When physicians provide patient contact information to researchers and researchers contact patients directly, patients can feel coerced, even if signed consent forms indicate that participation in the research project is voluntary. Patients might not want to offend their physicians or might be concerned that not participating in the research might affect their care. These factors require consideration when deciding whether to disclose patient information to researchers.

Physicians might decide not to provide contact information to researchers. Information about the research project could be given to patients directly. If this is done, there might be less perceived coercion because the physician leaves it up to the patient to contact the researcher.

## Health Information Act

The HIA sets out rules regarding the use and disclosure of health information for research purposes in Alberta. Legislation exists or is being developed in other provinces as well. Although there are many similarities across provinces and at the national level regarding personal health information protection, the application might be different among provinces. Legislation developed and enforced in Alberta might or might not be the same as legislation in other provinces, but the challenges are likely similar.

To avoid potential problems with disclosing health information, community physicians should adhere to the terms of disclosure for research provisions set out in their provincial health information legislation. It is wise to treat all health information in a standard manner according to the health information legislation so that, if a dispute arises, the physician will not be liable for breaching the law.

In Alberta, before disclosing health information, physicians are required by the HIA to obtain from researchers a written application for the disclosure of the health information as well as a copy of the research ethics board's approval letter. Consent to release specific health information needs to be obtained from patients if consent conditions have been imposed by either the research ethics board or the disclosing physician (custodian). Finally, with research projects requiring release of health information, physicians and researchers need to sign a research agreement. The Alberta Medical Association has developed a template for such agreements.

In Alberta, physicians can bill for preparing the information for disclosure, making copies of the health information, and obtaining consent; however, the costs must not exceed the actual cost of providing the service. The Alberta Office of the Information and Privacy Commissioner produced a publication to guide researchers, custodians, and ethics committees regarding use and disclosure of health information for research purposes; it can be accessed from **www.oipc.ab.ca**.

With increased awareness of the importance of accessing patients in non-academic settings, community physicians are becoming increasingly involved in research activities. With an understanding of potential ethical and legal concerns and adherence to legislation to protect patients' personal information, you can avert problems or concerns that could otherwise arise.

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