



College of Physicians and Surgeons of British Columbia

Professional Standards and Guidelines

Conflict of Interest Arising from Clinical Research

Preamble

This document is a guideline of the Board of the College of Physicians and Surgeons of British Columbia.

Over recent years, the biotechnology and pharmaceutical industries have expanded their research activities and increased their funding of clinical trials. While research conducted by physicians involving human subjects is critical to ongoing medical advancement, physician investigators who participate in these trials must be mindful that tensions can occur between science and quality care of volunteer patients. Physicians who operate as both clinician and investigator must conscientiously manage the ethical complexity of potentially competing loyalties.¹

Historically, clinical research was conducted in academic settings where research ethics boards (REBs) assumed responsibility for accrediting and validating the efficacy and conduct of clinical trials. However, due to increased industry funding and a growing competitive demand for timeliness, many clinical trials have moved outside of the academic arena, and are now being conducted at the community level where physicians in private practice are recruited directly to participate, and the ethical review board process may not be as rigorously monitored.

This shift towards independent industry-physician partnerships has raised a number of legitimate concerns, including ensuring data integrity, the need to strictly monitor research methodologies and protocols, and the potential for physician conflict of interest. Physicians who get involved in clinical trials are obligated to ensure that optimal patient care will continue, and that the study is scientifically sound. Physicians should be aware of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, which addresses the need for high ethical standards in research involving human subjects. In addition, physicians should ensure that they have adequate liability coverage at all times.

The following describes the College's position on conflict of interest arising from clinical research as it relates to physicians practicing in BC. It is supported by guiding ethical principles.

College's Position

Physicians should consider first the interests and well-being of their patients and avoid any situation that is, or may be reasonably perceived as, a conflict of interest. In any situation where

there is potential for conflict of interest in clinical research, registrants should seek advice from the College.

The following guidelines should assist physicians who are engaged in clinical research.

Compensation and Reward

Although advances in medical care depend on sound clinical research, the pursuit of science by clinical investigators can compromise a physician's duty to act in the patient's best interest.

When a physician is offered compensation or reward for participating in clinical research, there is the potential for conflict of interest. While some conflicting interests are inherent in research, such as grants or promotions through research and publication of findings, ethical problems arise if a physician's personal or financial interest in the research diminishes his/her ability to be objective in the provision of patient care. In extreme cases, a lack of objectivity may lead a physician to overestimate the benefits or downplay the risks associated with the therapeutic intervention, which can erode patient trust and lessen the integrity of the research.

Conflict of interest in clinical research may exist when:

1. A physician accepts a fee, gift or other incentive for finding and recruiting research subjects, especially if the research subject is his/her patient;
2. A physician accepts a fee for successfully completing a study within a set timeframe;
3. A physician participates in a clinical research trial conducted by a company in which he/she holds a financial interest.

It is considered reasonable and acceptable for physicians to be compensated at fair market value for any time they spend conducting the clinical research, for loss of income, and for any related expenses they incur during the study. Research subjects should be informed if their physician is receiving a fee for participating in the study.

Obligations

Before agreeing to participate in clinical research, physicians must ensure that the study has been appropriately evaluated and approved by a recognized and reputable research ethics board that adheres to Canadian standards and guidelines. The following principles from the Canadian Medical Association (CMA) have been adopted and endorsed by the College.

1. The primary objective of professional interactions between physicians and industry should be the advancement of the health of Canadians rather than the private good of either the physicians or industry.
2. Relationships between physicians and industry should be guided by the *CMA Code of Ethics*.
3. The physician's primary obligation is to the patient. Relationships with industry are appropriate only if they do not negatively affect the fiduciary nature of the patient-physician relationship.
4. Physicians should resolve any conflict of interest between themselves and their patients resulting from interactions with industry in favour of their patients.

5. In any relationship between a physician who is not an employee of the company doing the research and the company itself, the physician should maintain professional autonomy, independence and commitment to the scientific methodology.
6. A prerequisite for physician participation in industry-sponsored research activities is evidence that these activities are ethically defensible, socially responsible and scientifically valid. The physician's primary responsibility is the well-being of the patient.
7. The participation of physicians in industry-sponsored research activities should always be preceded by formal approval of the project by an appropriate ethics review board. Such review should follow national guidelines.
8. Patient enrollment and participation in research studies shall occur only with the full, informed, competent and voluntary consent of the patient or his or her proxy, unless the research ethics board authorizes an exemption to the requirement for consent.
9. The physician who enrolls a patient in a research study has an obligation to ensure the protection of the patient's privacy.

Definitions

Conflict of Interest

The term conflict of interest refers to circumstances where a primary interest (such as patient health) is compromised by a secondary interest (such as financial profit). It describes a clash between a physician's duty to act in the patient's best interest, and that physician's opportunity for personal gain. Physicians are required to make professional decisions based on the best interest of their patient, without any potential for personal benefit.

Informed consent

A physician is obliged to disclose all relevant information to potential research subjects to enable them to make an informed decision about whether or not to participate. This includes the information about the purpose of the study, its source of funding, the nature and relative probability of harms and benefits, and the nature of the physician's participation. A patient must provide consent willingly and voluntarily without duress, coercion or misrepresentation. To avoid any possible misunderstanding, in circumstances where an existing patient-physician relationship exists, it is advisable that a neutral third party who is not connected to the research trial obtain the consent on behalf of the physician investigator.

Therapeutic Misconception

Physicians have a responsibility to effectively communicate and not distort the potential benefits and risks of a research study to their patients. Patients may inaccurately believe that a new drug therapy, although experimental, must be superior to existing options. This misguided perception may lead patients to assume that the invitation to participate in a research study is, in fact, an individualized treatment plan recommended by their physician. This gap in understanding has been referred to as therapeutic misconception.²

Physicians have an obligation to ensure that their patients are adequately informed before entering a research study, that they know they are under no obligation to participate, and that their decision not to participate will have no adverse effect on the patient-physician relationship and the quality of care which is provided.

Compensation³

Compensation includes both financial and non-financial rewards, gifts, incentives and benefits. Non-financial compensation includes non-cash gifts, benefits or rewards such as objects, trips that are not directly relevant to the study, or academic benefits. Financial compensation includes, but is not limited to, loans, credits, and fees including finder's fees and completion fees. While it is appropriate and reasonable for physicians to be compensated at fair market value for any time they spend conducting the clinical research, for loss of income, and for any related expenses they incur during the study, accepting compensation over and above a fair market exchange has the potential for conflict of interest.

Finder's Fees³

A finder's fee is money or other reward given by the sponsoring company to a physician in payment for recruiting a patient into a study or trial. Finder's fees include bonus or milestone payments for successfully enrolling a particular number of patients or for successfully meeting a deadline in recruiting patients. Accepting finder's fees is considered unethical practice for physicians.

Completion Fees³

A completion fee is a payment granted by the sponsoring company to a physician for each patient's successful completion of the clinical study or for successfully completing the study within a specific period of time. Completion fees can include bonus or milestone payments. Accepting completion fees is considered unethical practice for physicians.

Guiding Ethical Principles

CMA Code of Ethics

Fundamental Responsibilities

1. Consider first the well-being of the patient.
2. Practice the profession of medicine in a manner that treats the patient with dignity and as a person worthy of respect.
7. Resist any influence or interference that could undermine your professional integrity.

Responsibilities to the Patient

11. Recognize and disclose conflicts of interest that arise in the course of your professional duties and activities, and resolve them in the best interest of the patients.
12. Inform your patient when your personal values would influence the recommendation or practice of any medical procedure that the patient needs or wants.
13. Do not exploit patients for personal advantage.
14. Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient.

Research

38. Ensure that any research in which you participate is evaluated both scientifically and ethically and is approved by a research ethics board that meets current standards of practice.

39. Inform the potential research subject, or proxy, about the purpose of the study, its source of funding, the nature and relative probability of harms and benefits, and the nature of your participation including any compensation.
40. Before proceeding with the study, obtain the informed consent of the subject, or proxy, and advise prospective subjects that they have the right to decline or withdraw from the study at any time, without prejudice to their ongoing care.

Responsibilities to the Profession

49. Be willing to participate in peer review of other physicians and to undergo review by your peers. Enter into associations, contracts and agreements only if you can maintain your professional integrity and safeguard the interests of your patients.
50. Avoid promoting, as a member of the medical profession, any service (except your own) or product for personal gain.

Acknowledgements

In developing this guideline on Conflict of Interest Arising from Clinical Research, the College referred to and cites several documents produced by other organizations, including existing policy papers from the Royal College of Physicians and Surgeons of Canada, the Canadian Medical Association, the Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans, the Colleges of Physicians and Surgeons of Alberta, Manitoba, Ontario and Nova Scotia, the Faculty of Medicine, University of Toronto, and the American Medical Association.

End Notes

¹ Source: Miller, Rosenstein, DeRenzo, Professional Integrity in Clinical Research, JAMA, October 28, 1998-v.280, n.16, p.1449

² Source: Chen, Miller, Rosenstein, Clinical Research and the Physician-Patient Relationship, Annals of Internal Medicine, 2003, v.138, n.8, p.669-670.

³ The definition of Compensation has been adopted from the College of Physicians and Surgeons of Ontario. The definitions of Finder's Fees and Completion Fees have been adopted from the University of Toronto's Policy on the Offer and Acceptance of Finder's Fees or Completion Fees in Research Involving Human Subjects.

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