

## CAUT Report: Relevant Recommendations (1, 10-14, 25, 26)

### General

**1** All contracts, protocols and investigator agreements for industrial sponsorship of clinical trials should expressly provide that the clinical investigators shall not be prevented by the sponsor (or anyone) from informing participants in the study, members of the research group, other physicians administering the treatment, research ethics boards, regulatory agencies, and the scientific community, of risks to participants that the investigators identify during the research. The same provisions should apply to any risks of a treatment identified following the conclusion of a trial in the event there are patients being administered the treatment in a non-trial setting.

Certain circumscribed confidentiality restrictions may be appropriate, for example, those pertaining to information on the chemical structure, or synthesis of a drug, or its method of encapsulation. However, restrictions on disclosure of risks to patients are not appropriate, subject only to the condition that the investigator believes there is a reasonable basis for identification of the risk. Under the term “risk” we include inefficacy of the treatment, as well as direct safety concerns.

### Research Ethics Boards

**10** Not only all protocols but also all associated research contracts and investigator agreements should be reviewed and approved by Research Ethics Boards (REBs) to ensure, among other things, that they comply with recommendation 1.

The REBs should ensure that the wording of protocols is congruent with their associated contracts and investigator agreements. REBs should have, and should exercise, the power to withhold approval of any proposed study if any of the associated protocols, contracts and investigator agreements contain inappropriate confidentiality clauses. REBs should be permitted to delegate the authority to conduct reviews of contracts and investigator agreements to the institutional office of research services. However, such delegation should only be done if:

- a) the office is given clear instructions that contracts and investigator agreements must comply with recommendation 1, with the protocols approved by the REB, the ethical standards articulated in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* and other norms of research ethics; and
- b) there is an annual process of auditing by the REB of a representative sample of contracts and investigator agreements to ensure consistency between the protocols (and ethical standards) and the contracts and investigator agreements.

**11** REBs should ensure that the guidelines in recommendation 10 are understood and followed by all sponsors and investigators. Insertion of the following text in the relevant documents is recommended:

#### a) *Consent form*

Throughout the research process, you will be given any new information that might affect your decision to participate in the research. In particular, you will be told of any unforeseen risks that may be identified.

*b) Protocol*

No agreements or contracts between researchers and sponsors that limit the right and the responsibility of the researchers to disclose relevant information about unforeseen risks that becomes known in the course of the research, to participants in the study, members of the research group, other physicians administering the treatment, research ethics boards, regulatory agencies, and the scientific community, have been or will be entered into by the researchers.

*c) Investigator agreements / contracts*

If I have concerns about the safety and/or efficacy of the study drug, X, I have the right and the responsibility to disclose relevant information that becomes known to me in the course of the research, to participants in the study, members of the research group, other physicians administering the treatment, research ethics boards, regulatory agencies, and the scientific community.

**12** REBs should review project budgets as well as the research protocols and associated contracts and agreements, in order to ensure that all actual and potential conflicts of interests are managed in an ethical fashion.

**13** REBs should ensure that protocols and related contracts and agreements make express provision for the management of patient care in the event of premature termination of a research trial, and should withhold approval of the study until such provision has clearly been made.

**14** REBs should review institutional policies and practices with respect to access to patient records for research purposes to ensure that they are in compliance with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)*.

***Granting Councils***

**25** In order to help ensure consistency in standards across the country, the Canadian Institutes for Health Research (CIHR), together with the Social Sciences and Humanities Research Council (SSHRC) and the Natural Sciences and Engineering Research Council (NSERC), should impose a requirement that universities and health care institutions receiving any funding from the granting councils have in place the policy in recommendation 1. The requirement should apply to all clinical research projects conducted at these institutions, whether or not such projects are funded by one of the granting councils. A means of ensuring compliance would be the withholding of all CIHR, SSHRC and NSERC funds where such a requirement is not in place, or is not met, and the Councils should actively monitor compliance.

**26** The *TCPS* should be amended so as to give further explicit and prescriptive direction to REBs on the need and ways to identify and manage conflicts of interest.