

[Section 4]

CONFLICT OF INTEREST

Researchers hold trust relationships with research subjects, research sponsors, institutions, their professional bodies and society. These trust relationships can be put at risk by conflicts of interest that may compromise independence, objectivity or ethical duties of loyalty. Although the potential for such conflicts has always existed, pressures to commercialize research have led to increased concerns. Researchers, their institutions and REBs should identify and address conflicts of interest—real or apparent—to maintain the public confidence and trust, discharge professional obligations and ensure accountability.

Article 4.1

Researchers and REB members shall disclose actual, perceived or potential conflicts of interest to the REB. REBs should develop mechanisms to address and resolve conflicts of interest.

A. Conflicts of Interest Involving Researchers

The REB should assess the likelihood that the researcher's judgement may be influenced, or appear to be influenced, by private or personal interests, and assess the seriousness of any harm that is likely to result from such influence or from the mere appearance of undue influence. Competing interests may arise from family relationships, financial partnerships or other economic interests.

The appearance of a conflict may in some cases be as damaging as a real conflict. Two approaches can be suggested for assessing the potential implications of apparent or real conflicts of interest. One might ask whether an outside observer would question the ability of the individual to make a proper decision despite possible considerations of private or personal interests; alternatively, one might ask whether the public would believe that the trust relationship between the relevant parties could reasonably be maintained if they had accurate information on the potential sources of conflict of interest.

When a significant real or apparent conflict of interest is brought to its attention, the REB should require the researcher to disclose this conflict to the prospective subjects during the process of free and informed consent. In accord with Article 2.4(e), research subjects should be fully informed of a researcher's potential or actual conflict of interest. To identify and address conflicts properly, REBs should be provided with details on the research project, budgets, commercial interests, consultative relationships and other relevant information (see Article 7.3).

REB management of conflicts of interest requires a proportionate approach. Sometimes, the conflict of interest is so pervasive that it is not enough merely to disclose it to the research subjects, the sponsors of research, institutions, relevant professional bodies or the public at large. In such instances, the REB may require that the researcher abandon one of the interests in conflict. A conscientious researcher will, under such circumstances, either withdraw from the research or allow others to make research-related decisions without being directed to do so. However, in some cases, the REB might conclude that the identified conflict of interest does not warrant specific

actions. When significant conflicts of interest are identified, the continuing ethics review process by the REB may also help to manage them (see Section 1). When a conflict of interest is unavoidable, the continuing ethics review process should be made more stringent, to help ensure that conflicts are managed appropriately.

B. Conflicts of Interest by REB Members

To maintain the independence and integrity of ethics review, it is of the highest importance that members of the REB avoid real or apparent conflicts of interest (see Article 1.12). For example, REB members are in a clear conflict of interest when their own research projects are under review by their REB or when they have been in direct academic conflict or collaboration with the researcher whose proposal is under review. To manage such conflicts, REB members must withdraw from the committee when such projects are under consideration. In some instances, individual members of the REB may also have a conflict of interest in accepting undue or excessive honoraria for their participation in the REB (e.g., on commercial REBs).

C. Institutional Conflicts of Interest

The REB must act independently from the parent organization. Therefore, institutions must respect the autonomy of the REB and ensure that the REB has the appropriate financial and administrative independence to fulfil its primary duties. Situations may arise where the parent organization has a strong interest in seeing a project approved before all ethical questions are resolved. As the body mandated to maintain high ethical standards, however, the public trust and integrity of the research process require that the REB maintain an arm's-length relationship with the parent organization and avoid and manage real or apparent conflicts of interest.