

**Reference from the Granting Agencies to the  
Interagency Panel on Research Ethics:  
TCPS Research Ethics Matters Raised by the Olivieri Report**

*The Presidents of the CIHR, NSERC, and SSHRC,*

**Recognizing**

- That recent developments and reports in Canada have given prominent international attention to a range of issues raised by constraints on the non-disclosure of risk information to participants in clinical trials and human research;
- That this and related issues have been discussed in particular in Recommendations 1 and 25 of the *Report of the Committee of Inquiry on the Case Involving Dr Nancy Olivieri, the Hospital for Sick Children, the University of Toronto and Apotex Inc.* (CAUT Olivieri Rpt., 2001) and other important public reports, whose contents and recommendations have been brought to the attention of the Granting Agencies;
- That the issues identified in these reports implicate the national research ethics interest by raising significant policy issues for the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS);
- That such policy issues specifically implicate TCPS standards and procedures concerning, amongst other issues, the informed consent of participants; conflicts of interest; the conduct of clinical trials; researchers' ethical duties; and the continuing monitoring duties of REBs and institutions;
- That the broad research ethics community which uses the TCPS may benefit from further clarity, precision, and guidance on these issues and developments;
- That the independent reflection and advice of pluralistic, interdisciplinary ethics entities may prove instrumental in developing such guidance;

- That the Granting Agencies have recently created the Interagency Advisory Panel on Research Ethics (PRE) to serve such a role, and have delegated to PRE the responsibility to articulate recommendations for the further development and evolution of the TCPS;
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**Therefore, Request the Interagency Advisory Panel on Research Ethics to:**

- *Review* (a) the recommendations 1 and 25 of the Olivieri report, as they relate to the disclosure of risk information in clinical trials, (b) other directly relevant recommendations and analyses contained in this and other reports and literature; and (c) pertinent international and national developments and institutional policies, in light of the need to keep the TCPS current with modern research ethics needs; and
- *Consult* with appropriate experts, interests, and stakeholders, including the public; and
- *Report and Advise*, in a timely manner to the Presidents of the three Agencies, on whether, when and how to incorporate proposed recommendations for amendment of the TCPS.

Ottawa, \_\_\_\_\_ May 2003.

Dr Alan Bernstein  
President, Canadian Institutes of Health Research

Dr Tom Brzustowski  
President, Natural Sciences and Engineering Research Council of Canada

Dr Marc Renaud  
President, Social Sciences and Humanities Research Council of Canada