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Confusion Worse Confounded: A Comment on 'Withdrawal of Clinical Trials Policy by Canadian Research Institute is a 'Lost Opportunity for Increased Transparency'

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Withdrawal of clinical trials policy by Canadian research institute is a “lost opportunity for increased transparency”

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Rapid Response:

"Confusion worse confounded" [1]

According to a recent BMJ article on CIHR's decision to "disappear" its policy on clinical trial registration, "Ian Graham, CIHR's vice president Knowledge Translation and Public Outreach, stated the CIHR policy was removed 'as the overlap [with Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)] will cause confusion and inconsistent application of the requirements.'" [2]

Ironically, this explanation is itself confusing and inconsistent with previous decisions made by CIHR. There are at least three areas in which CIHR policy/guidelines overlapped with TCPS 2 (registration and results disclosure of trials, research involving Aboriginal People, and research involving human pluripotent stem cells), and in each case CIHR took a different approach.

First, as regards registration and results disclosure of trials, CIHR declared that TCPS 2 "supersedes" the "Policy on registration and results disclosure of controlled and uncontrolled trials funded by CIHR" and removed the policy from its website. [3]

Second, as regards research involving Aboriginal People, CIHR declared that "the CIHR Guidelines for Health Research Involving Aboriginal People are no longer CIHR funding policy. Health research involving First Nations, Inuit and Metis people in Canada is henceforth governed by the provisions outlined in Chapter 9 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)."[4] At first glance, this might appear consistent with the approach taken with

respect to registration and results disclosure, but there are important differences. CIHR has not removed these guidelines from its website. Moreover, the Introduction to Chapter Nine of TCPS 2, states that "[t]he CIHR Guidelines remain an important source of additional guidance for health research involving Aboriginal peoples in Canada." [5]

Third, as regards research involving human pluripotent stem cells, CIHR elected to retain the "Guidelines for Human Pluripotent Stem Cell Research" (originally drafted by CIHR in 2002 and since then endorsed and periodically updated by the three federal funding councils). [6] In line with this decision, TCPS 2 states that "Researchers who intend to conduct research to derive or use pluripotent stem cells shall follow the Guidelines for Human Pluripotent Stem Cell Research, as amended from time to time and published by the Canadian Institutes of Health Research." [7]

If anything is going to cause "confusion and inconsistent application", it is the inconsistent (and, we would argue, ethically indefensible) ways in which these CIHR policy/guidelines have been treated in relation to TCPS 2.

[1] Milton, J Paradise Lost, ii. Line 996.

[2] BMJ 2011;342:d2570

[3] <http://www.cihr-irsc.gc.ca/e/42831.html> accessed May 3, 2011

[4] <http://www.cihr-irsc.gc.ca/e/29134.html> accessed May 3, 2011

[5] http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf at page 106 accessed May 3, 2011

[6] <http://www.cihr-irsc.gc.ca/e/42071.html> accessed May 3, 2011

[7] http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf at page 179 accessed May 3, 2011

Competing interests: Francoise Baylis - former member of the CIHR Governing Council and current member of the CIHR Institute of Gender and Health. Jocelyn Downie -- none declared

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