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Health Canada: Update on Activities

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Outline

- Canadian General Standards Board: Research Ethics Boards Overseeing Biomedical Clinical Trials
- Health Canada Guidance: Biobanking of Human Biological Materials
- Management of Adverse Event Reports by Research Ethics Boards
- International Activities
- Health Canada Centre of Expertise in Bioethics




Canadian General Standards Board

- The scope of the standards is limited to REBs overseeing clinical trials as defined by Health Canada regulations.
- The standards are being developed through the CGSB process managed by a committee of over 30 organizations across Canada, of which Health Canada is a member.
- The standards are voluntary.
- It is expected that the standards will go to vote in June.
- Health Canada plans to assess the uptake and effectiveness of the standards as they become accepted by the clinical research community.




Guidance for Health Canada (HC): Biobanking of Human Biological Materials (HBM)

- Identified need for comprehensive guidance to address biobanking activities at HC
 - carried out under contract with HC, and/or
 - funded by HC grants/contributions e.g. in collaboration with external researchers
- Overview of Guidance:
 - Consistent with OECD and other related biobanking guidance
 - Addresses topics such as governance, recruitment, consent, collection, storage, processing, and handling
 - Several rounds of consultation with health portfolio and with Canadian experts
- Publication anticipated for late 2010



Management of Adverse Event Reports by Research Ethics Boards

- Health Canada is conducting a policy review of the management of adverse event (AE) reports by REBs in multi-centre clinical trials (MCTs)
 - Identifying challenges in management of AE reports
 - Considering recent, ongoing, and potential initiatives that may impact the situation and influence the development of a solution
 - Considering and developing options for addressing the issues



International Activities

- Council of Europe
 - Steering Committee on Bioethics (CDBI)
- OECD
 - Development of Guidelines for Human Biobanks and Genetic Research Databases
- UNESCO
 - Intergovernmental Bioethics Committee (IGBC)/ International Bioethics Committee (IBC)
 - liaison with the Canadian Commission for UNESCO (CCU)



Centre of Expertise in Bioethics

- In recognition of Health Canada's role as the federal lead for bioethics, the Department is establishing a Centre of Expertise in Bioethics.
- Activities will include:
 - Providing strategic quality advice to the Minister of Health;
 - supporting Health Canada in delivering sound ethics-related advice on federal interests including federally funded research activities;
 - building upon and strengthening existing relationships with the ethics community;
 - seeking out and developing new opportunities for collaboration and partnership;
 - sharing federal perspectives and networking across national and provincial boundaries to further the shared interests of the Dept and research ethics communities;
 - representing the federal government and Canadian perspective in domestic and international fora; and
 - establishing a comprehensive program of work with a view to strengthening research participant protections in Canada.

