



Conjoint Health Research Ethics Board (CHREB)  
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### CHREB guideline for amendments, modifications, and investigator brochure updates

A core principle for ethical conduct for research involving humans is Respect for Persons. This principle incorporates the moral obligation to respect the autonomy of individuals. In the research context, individuals exercise their autonomy through decisions to providing their free, informed and ongoing consent for research participation.

For consent to be informed, people must have a complete understanding of the purpose of the research, what it entails and its foreseeable risks and potential benefits. Respect for persons is a commitment to accountability and transparency in the ethical conduct of research.

Consent is to be maintained throughout the research project and **researchers** have the ongoing responsibility to provide people taking part in research with all information relevant to their ongoing consent to participate in the research. The researcher has an ongoing ethical and legal responsibility to bring to participant's attention any changes to the research project that may affect them (Article 3.3, TCPS2).

In particular, researchers shall disclose changes to the risks or potential benefits of the research allowing participants the opportunity to reconsider the basis for their consent, and their continued participation in the study, in light of the new information.

*Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, TriCouncil Policy Statement: Ethical Conduct for research Involving Humans, December 2010.*

**When requesting an amendment or modification to an existing protocol, please indicate if the change(s) requested:**

- 1). Require an amendment to the current consent form. If yes, please submit the revised form.
- 2). Require that the revised information be provided to participants currently enrolled in the study trial.
  - If yes, please describe the manner in which this information will be communicated. If this will be through a consent addendum, please submit the addendum.
- 3). Require that an amendment be filed with Health Canada
  - If yes, please provide a copy of Health Canada's approval letter once received