Protocol Amendment Decision Tool

Major Amendments

- Adding a new activity that may increase risk to participants.
- Changing drugs or medications, alterations in the dosage or route of administration.
- Changing levels of radiation exposure.
- Adding a vulnerable population.
- Adding or changing invasive procedures.
- Adding a research arm to the study.
- Substantially extending the duration of exposure to the test material or intervention.
- Broadening the range of inclusion criteria
- Narrowing the range of exclusion criteria.
- Extending significantly the duration of a study.
- Removal of laboratory tests, monitoring procedures or study visits directed at gathering safety information.
- Appearance of new, serious unexpected adverse events or significant risks.
- New study documents to be distributed to or seen by participants that include information or questions substantively different from materials already approved by the HREC.

Minor Amendments

- Administrative or informational amendments:
  - Changing the study title or telephone numbers.
  - Addition or removal of qualified investigators, study sites.
  - Revision of format of consent documents, recruitment materials or questionnaires.
  - Correction of typographical errors.
  - Editorial changes that clarify but do not alter the existing meaning of a document.
  - Translations of materials already reviewed and approved by the HREC.
- Procedural amendments
  - Drawing slightly different amounts of blood, changing frequency at which blood is drawn.
  - An increase or decrease in proposed number of participants supported by a statistical justification.
  - Narrowing the range of inclusion criteria.
  - Broadening the range of exclusion criteria.

- Changing the amount of compensation, within reasonable limits.
- Revisions to the informed consent documents to improve clarity, to include missing elements or to revise lay language.
- Decreasing drug dosage or frequency of administration.
- Decrease in number of study visits provided such a decrease does not affect collection of relevant safety-related data.
- Alterations in oral forms of administration of a drug e.g. tablet to capsule or liquid, as long as the dose remains constant.
- Changing data collection points or amounts of data collected as long as it does not alter safety evaluations.
- An increase in safety monitoring resulting in more frequent visits or an increase in the length of hospitalisation.
- An increase or decrease in sample size, supported by a statistical justification.
- Changes in compensation with adequate justification.