**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.