

Budget Review

According to the Tri-Council Policy Statement (TCP) Article 7.3 “REBs shall examine the budgets of clinical trials to assure that ethical duties concerning conflict of interest are respected”.

The UHN REB examines the budgets of clinical trials for specific reasons and does this from the perspective of:

- o Feasibility
- o Coercion
- o Conflict of interest

In order to be ethical, clinical research must not only be scientifically valuable, but its completion must be feasible. Subjects should not be exposed to the risks and inconveniences of research unless it is reasonable to suppose that the scientific question can be answered. The budget is a powerful indicator of *feasibility*. The REB reviews the budget to establish whether it provides sufficient funds or other resources to ensure the timely completion of the study.

The REB also reviews the budget to observe for any unnecessary or unjustified costs. Hints of unexplained payments or expenses may raise questions about ethically inappropriate incentives or questions about the existence of *conflicts of interest*. For example, the budget should not include payment provisions that encourage rapid enrolment of subjects or higher per subject payments for those recruited above a set target. The REB must evaluate if this practice would encourage Investigators to recruit subjects who would not otherwise be appropriate, in order to reach higher paying thresholds.

The information in the budget should be consistent with what is described in all documents submitted for review and approval. For example, the REB reviews the budget to ensure that the provision for payments to subjects is reasonable and consistent with that disclosed in the submission.