

UBC – BCCA Research Ethics Board Guideline

Elements required of a pilot/feasibility study in human subjects

- 1) **Objectives:** State the objectives of the pilot/feasibility study. Some examples are:
 - a. to estimate the participation rate
 - b. to estimate the median, mean and standard deviation of a predictor or outcome measure
 - c. to estimate the median event-free, progression-free or overall survival in a patient group
 - d. to characterize the toxicity of an intervention, determining likelihood of occurrence, possible severity
 - e. to determine the convenience and time requirements of an intervention
- 2) **Eligibility:** Indicate the inclusion and exclusion criteria for subjects to be enrolled in the study.
- 3) **Relevance:** Describe the relevance of the pilot/feasibility study in relation to the objectives of the follow-up/main study. What will be learned from the pilot/feasibility study that will be of usefulness in conducting the follow-up/main study?
- 4) **Data Collection:** Describe specifically what will be measured in the pilot/feasibility study.
- 5) **Use of Information:** State how the information from the pilot/feasibility study will be used to determine whether to go ahead with the follow-up/main study and/or to assist with the design of the follow-up/main study.
- 6) **Analysis:** Describe the statistical analysis to be used in the pilot/feasibility study indicating the specific statistical techniques that will be used.
- 7) **Sample size:** State the sample size of the pilot/feasibility study and explain how the sample size was determined.