

### Appendix 3: Summary of Study Objectives and Data Analysis

**Table 1: Summary of Study Objectives and Data Analysis.**

Objective	Outcome	Factors	Hypothesis	Objective
Primary				
1) to assess whether pilot studies approved by the Hamilton Integrated Research Ethics Board transparently communicate the purpose of the study to participants through their informed consent practice.	Does the final consent form or patient information document: i) use the term “pilot” or “feasibility” in the title ii) define what a pilot or feasibility study is iii) clearly state the objectives of the study to assess feasibility iv) state the specific objectives of the study and v) state the criteria for the feasibility study to successfully lead to the main study.	Not applicable.	Not applicable.	Proportion of studies for each outcome including a 95% confidence interval, and the average number of items included.
Secondary				
1) To assess whether there is a difference between the original and revised versions of the informed consent forms specifically in addressing the issues and criterion discussed in the primary objective.	Is there a difference in the inclusion of items stated in the primary objective between the initial and final consent forms.	Initial consent form vs revised consent form	Revised versions will include more of the items stated in the primary objective.	Conditional logistic regression for each of the five criterion and adjusted for protocol characteristics.

2) To determine methodological characteristics associated with reporting or inclusion of the items in the primary question in the original consent form.	Is there methodological characteristics including: i) randomization ii) type of data collected iii) sample size and iv) the specific feasibility objectives assessed that are correlated with better inclusion of the items stated in the primary objective in the original consent forms.	1) randomization or non-randomization 2) quantitative, qualitative, or mixed methods 3) sample size 4) year of submission 5) observational or interventional 6) industry sponsored or not 7) specific feasibility objectives 8) pilot or feasibility studies	Not applicable.	Logistic regression.
3) To assess the consistency with which feasibility and pilot studies assess feasibility outcomes as their primary objectives.	Is there a difference between “pilot” and “feasibility” studies in their consistency of assessing feasibility as their primary objective.	Pilot studies vs feasibility studies vs both	Not applicable.	Proportion of studies primarily assessing feasibility for each factor including a 95% confidence interval.