**How to write a protocol to accompany a submission to the Baycrest REB**

Label the Protocol Appendix 1. It is not necessary to repeat this information on the application form. Refer to Appendix 1 when applicable. When amendments are made to the study protocols throughout the course of the study, the protocol document should be updated (new version number/date) and submitted.

**Background**

Briefly describe the overall objective of the study and previous work on the question. Explain how your new study fits into that background. Use lay language—this may be read by people not in your field, including community members on the Research Ethics Board

**Objectives**

The specific objectives of your study or your specific hypotheses.

**Participants**

Number, type, recruiting methods; include and justify inclusion and exclusion criteria. Use subsections for clarity. Include the recruitment methods you will use, who will recruit and obtain informed consent, and attach any recruiting posters and recruiting scripts as Appendix 3. Include the informed consent form in Appendix 2.

**Methodology**

The setting where the study will take place (Baycrest, at home, at another institution); recruitment process; measures you will use; time commitment. Use subsections for clarity. Include a copy of paper and pencil tests in Appendix 4. Include Data Collection forms in Appendix 6.

**Risks and Benefits**

Describe the risks and benefits of the study to the participant. Consider risks associated with physical, cognitive, and emotional measures.

**Justification of sample size**

**Data Management and Proposed analyses**

Describe the data management and analyses plan, and indicate how it allows testing of the specific objectives or hypotheses described above.

**Confidentiality of data**

Describe the measures to ensure the privacy and confidentiality of participant data. Include how/what data will be anonymized/deidentified and what will happen to the data during and after the study.

**Withdrawal of participants**

Describe what will happen when participants withdraw from the study. How will this affect the analysis plan? What will be done with their data? How will they be compensated?

**Incidental Findings**

Describe what type of incidental findings may be found and what procedures are in place to relay this information to participants and support them.