**STUDY PROTOCOL TEMPLATE (modified from WHO Recommendations)**

1. **GENERAL INFORMATION**

**• Protocol title, protocol identifying number (if any), and date.**

**• Name and address of the sponsor/funder (if any).**

**• Name and title of the investigator(s) who is (are) responsible for conducting the research, and the address and telephone number(s) of the research site(s), including responsibilities of each.**

**• Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the research**

1. **BACKGROUND AND RATIONALE**

Current environment that is the basis for the proposed research, the problem, and a review of current literature. There must be rationale (the reason) for conducting the research in light of current knowledge.

1. **HYPOTHESIS, GOALS, AND OBJECTIVES**

A hypothesis is an educated prediction that can be tested. Goals are broad statements of what the proposal hopes to accomplish. Objectives are statements of the research question(s); objectives should be simple, specific, and stated in advance. After statement of the primary objective, secondary objectives may be mentioned. Objectives should adequately support the primary or secondary hypothesis.

1. **STUDY DESIGN**

**The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology. The design of the study should include information on the type of study, the research population or the sampling frame, and who can take part (e.g. inclusion and exclusion criteria, withdrawal criteria etc.), and the expected duration of the study**

1. **METHODOLOGY**

Detailed information on the interventions to be made, procedures to be used, measurements to be taken, observations to be made, laboratory or clinical investigations to be done etc. If multiple sites are engaged in a specified protocol, methodology should be standardized and clearly defined. A graphic outline of the study design and procedures may be provided for clarity. This should include the timing of the intervention and/or assessments. The protocol should specify the time that each phase of the project is likely to take, along with a detailed month by month timeline for each activity to be undertaken.

1. **SAFETY CONSIDERATIONS**

Safety aspects of the research should always be kept in mind and information provided in the protocol on how the safety of research participants will be ensured. This may include identification of risks and benefits to study subjects and procedures for recording and reporting adverse events and their follow-up.

1. **DATA MANAGEMENT AND STATISTICAL ANALYSIS**

The protocol should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification. The statistical methods proposed to be used for the analysis of data should be clearly outlined, including reasons for the sample size selected, power of the study, level of significance to be used

1. **BUDGET**

The budget section should contain a detailed item-wise breakdown of the funds requested for, along with a justification for each item.

1. **LITERATURE CITED**

Additional Sections and Addenda may be required on a project specific basis. Please contact the RVH Research Office for support at research@rvh.on.ca or call 705 728-9090 x 41350