Protocol Guidelines for Research Ethics Review

A full Protocol / Proposal must accompany your Toronto Academic Health Sciences Network (TAHSN) Short Form or your Toronto Academic Health Sciences Network (TAHSN) Long Form.

Your Protocol must include the full study title, an identifying number (version code), a version date, and the full name of the Principal Investigator. Any amendments should bear the amendment version number, and version date – clearly distinguishing each version of the protocol.

Element(s)	Description
▪ Research Title	– Should be clear, concise, and meaningful. – It should be free of jargon and overstatement. – It should be formal.
▪ Introduction ▪ Background ▪ Purpose	– What motivated your research topic? – Why does your research topic matter? – How will your research contribute to the field?
▪ Summary ▪ Significance	– Research questions and hypotheses. – Identify gaps in current knowledge and how your work will fill them. – Stress the importance of your work. Include preliminary results, if available. – Brief description of your actual work. – Brief description of techniques, sites, terminology. – Projected results or output. – How your work will advance the research area. – Broader significance of the work.
▪ Research Questions	– Formulate the questions your research will investigate. Questions should not be too broad or too specific. – Research questions should derive from your methodological framework and literature review. – Research questions should be connected to each other (as opposed to being a disparate set) and be organized in a logical manner.
▪ Research Plan ▪ Intervention ▪ Objectives	– Overview of research design. – Give a brief description of the design. – Give enough detail for evaluating the design, not for replicating the work.
▪ Project Description ▪ Design	– Focus on projects that are similar to the current project or that form the basis for the current project. – Problem and significance.

▪ Ethics ▪ Feasibility	– What are the empirical and theoretical outcomes of your work? – What are the uses of the data? – What are the long-term implications of the project? – Explain how your research will contribute to the current body of knowledge.
▪ Methodology ▪ Theoretical Framework	– A well-known method must be referenced. – Describing the method in general terms may be sufficient. – A novel or unknown method must be described in detail. – If the method is not original, it must be referenced. – Explain which methodological framework (e.g., theories, hypotheses, and instruments) will be employed. – Describe the methodology; explain why you chose it and how you will use it. – If your research involves the collection and analysis of research assets (e.g., photos, audiovisual recordings, texts) or data, explain how you will collect, manage, and preserve them (e.g., interviews, ethics application, and questionnaires). – Discuss the tools employed for their interpretation (e.g., models, programs). – Discuss possible limitations arising from your methodology.
▪ Objectives ▪ Hypotheses ▪ Specific Aims ▪ Anticipated Outcomes	– Should be few, focused, and testable. – Should closely relate to experimental methodology. – What is the best for the current research? – Are they proven and cited? – Are they feasible and practical (time, funding, data analysis, investigator competence)? – Do they result in realistic and important output (based on the significance statements)? – Do the aims grow out of the hypotheses? – Explain what is needed to realize the aim. – Primary endpoints and the secondary endpoints, if any to be measured during the trial.
▪ Risk/Benefits ▪ Compensation	– Insert summary of the known and potential risks and benefits, if any. – Describe any compensation to participants (e.g., travel expenses, snacks)
▪ Recruitment ▪ Population ▪ Participants ▪ Consent Process	– Description of the population to be studied. – Will substitute decision-makers be required? – Are special populations involved? – Are the rights and welfare of potentially vulnerable subjects protected?

▪ Setting ▪ Procedures	– What is the sample size? – What is the method of contacting participants? – How/where will participants be enrolled, and consented? – What are the inclusion criteria /exclusion criteria? – What are the participant withdrawal criteria (i.e., terminating investigational product treatment/trial treatment) and procedures? – Where will the research take place?
▪ Data Handling ▪ Data Collection ▪ Record Keeping ▪ Data Analysis ▪ Measurement Tools ▪ Privacy and Confidentiality	– Insert a description of who, what, where and why. – Procedures for obtaining data should be clearly stated. – Ensure all data handling procedures are described in detail and in accord with current privacy legislation. – Are there adequate safeguards to protect confidentiality of data? – Have the absolute minimal amount of participant identifiers been considered for collection if required? Can these be justified?
▪ Timetable ▪ Publication ▪ Final Reports	– Give the beginning and end of recruitment periods. – Estimate time needed for construction or purchase of equipment, development of a technique, acquiring or developing needed materials. – Include time allocation for each significant stage of the research while allowing extra time for approval/review by the supervisory committee, ethics committee as well as for data collection and interpretation. – Expected duration of project. – Indicate when results will be published and what these plans are. – If results will be provided to participants.
▪ References	– References should be directly related to your project. – Selection should be unbiased. – Cite mostly peer-reviewed sources. – Include only essential references. – Be sure all citations are accurate. – Use mostly recent papers. – Check spelling, especially for proper names and references in foreign languages.
▪ Budget ▪ Funding ▪ Sponsorship	– Research the project to estimate accurate costs. – Check to see if there are any institutional/departmental impacts and negotiate these prior. – Understand the ethical requirements of asking for funding.

	Budgeting Categories: – Salaries (indicate period to be worked) – Equipment (usually defined by the granting agency) – Supplies (expendable items) – Travel (mileage, number of trips, lodging, food; justify these and destinations) – Miscellaneous expenses (e.g., courier services, computer time, etc.) – Indicate any cost-sharing arrangements that may exist. – Departmental costs *Funding Categories*: – List any grants that you have received/applied for and the amounts. – List any sponsorship and the amounts.

Important note:

▪ Literature Review	– Select the most important papers that support your work. – Select the most important papers that come to contrary conclusions. – Thoroughly understand any controversy in the field. – Be certain of any gap that you try to establish. – Stay focused and concise. – Define and limit your area of interest along with the parameters of your study. – Consult a variety of databases, indexes, and bibliographies to determine a current and relevant body of knowledge.

Your protocol should be at minimum one page in length, and you should attempt to incorporate as many of the elements listed as possible.

When writing your protocol, do not duplicate (copy & paste) the information you provided in your TAHSN application form or vice versa. It should be similar information however your protocol is meant to provide a more fulsome description of the research plan for the Research Ethics Board reviewer.