

Protocol Guidelines for Research Ethics Review

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

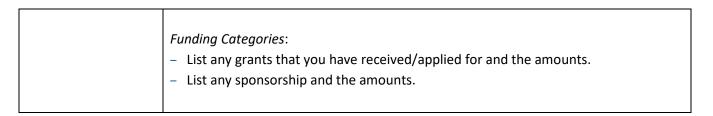
Your Protocol must include the full study title, an identifying number (version code), a version date, and the full name of the Principal Investigator. Any amendments should bear the amendment version number, and version date – clearly distinguishing each version of the protocol.

Element(s)	Description
Research Title	 Should be clear, concise, and meaningful.
	 It should be free of jargon and overstatement.
	 It should be formal.
Introduction	What motivated your research topic?
Background	Why does your research topic matter?
Purpose	How will your research contribute to the field?
Summary	Research questions and hypotheses.
Significance	 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	- Overview of research design.
Intervention	 Give a brief description of the design.
Objectives	 Give enough detail for evaluating the design, not for replicating the work.
ProjectDescription	 Focus on projects that are similar to the current project or that form the basis for the current project.
Design	 Problem and significance.

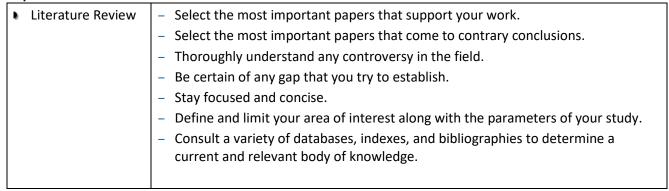
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. F:	thics	What are the empirical and the eretical outcomes of your world
		What are the empirical and theoretical outcomes of your work?What are the uses of the data?
• F	easibility	
		What are the long-term implications of the project?
		 Explain how your research will contribute to the current body of knowledge.
• N	/lethodology	A well-known method must be referenced.
	heoretical	 Describing the method in general terms may be sufficient.
F	ramework	 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 a social a limitation of a pricing from a control of the delay.
		 Discuss possible limitations arising from your methodology.
• O	Objectives	Should be few, focused, and testable.
▶ H	lypotheses	 Should closely relate to experimental methodology.
▶ S	pecific Aims	– What is the best for the current research?
A	nticipated	– Are they proven and cited?
0	Outcomes	 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? Evelop what is peopled to realize the sim.
		Explain what is needed to realize the aim. Primary and points and the secondary and points if any to be measured during the
		 Primary endpoints and the secondary endpoints, if any to be measured during the trial.
▶ R	tisk/Benefits	 Insert summary of the known and potential risks and benefits, if any.
	Compensation	Describe any compensation to participants (e.g., travel expenses, snacks)
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	Recruitment	Description of the population to be studied.
▶ P	opulation	Will substitute decision-makers be required?
	articipants	Are special populations involved?
• C	Consent Process	Are the rights and welfare of potentially vulnerable subjects protected?
■ See	etting	- What is the sample size?
• P	rocedures	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

 Data Handling Data Collection Record Keeping Data Analysis Measurement Tools Privacy and Confidentiality 	product treatment/trial treatment) and procedures? - Where will the research take place? - 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?
TimetablePublicationFinal 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



Important note:



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.