

JUNE 2001

SCIENCE SUB-COMMITTEE REVIEW APPLICATION FORM

MULTICENTER STUDY/CLINICAL TRIAL

Request to Participate

OBJECTIVES

1) A brief statement of the objective(s) of the study.

2) Rationale

A discussion of the justification for the study, i.e. what is the reason for performing the study. If in the case of a clinical trial the current therapy is inadequate explain why it is inadequate and discuss the number and type of patients who are affected by the disorder.

3) Background

It will be necessary for the CHEO investigator to provide the relevant background information to educate the Science Sub-Committee about the type of disorder being treated and contrast current therapy with that proposed in the study. If the background material is adequately discussed in the multicenter grant application, refer to those portions (pgs) of the proposal.

b) For a multicenter center study, if the background material is adequately discussed in the multicenter grant application, refer to those portions (pgs) of the proposal.

4) Details of the Experimental Design

Briefly describe how the study is to be performed, time course, measurements made, data collected and analyzed. Discuss potential risk factors.

5) Investigators

Statement of names of all CHEO investigators involved in the study and their role.

6) Patient Recruitment

Indicate source and number of patients to be involved in the study, i.e.; ambulatory clinic, neurology clinic.

7) Inclusion - Exclusion Criteria

Briefly summarize or refer to a page # in the application supplying this information.

8) Risk Factors

Describe known or possible risks and how they will be handled, i.e. what precautions will be taken?

9) Source of Funding

Indicate source of funding and what is covered by these funds. If further support is required from another CHEO investigator who is not a co-applicant or co-investigator, e.g. creatinine measurements - CHEO - Biochemistry - statement from Director of Biochemistry indicating his/her agreement to perform these measurements.

10) Consent Form

Consent form on CHEO letterhead must be presented with the proposal. Describe how it will be presented.

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**MULTICENTER STUDY/CLINICAL TRIAL CHECK LIST**

The following have been dealt with in the proposal:

YES	NO	
___	___	If this is a randomized controlled trial, completed Consort Check List is attached - checklist is available at: <a href="http://www.consort-statement.org">http://www.consort-statement.org</a>
___	___	Statement of objective(s)
___	___	Rationale for the study
___	___	Background information
___	___	Description of Experimental Design
___	___	List of CHEO investigators participating
___	___	Source of patient recruitment
___	___	Inclusion - Exclusion Criteria
___	___	Known or possible risks
___	___	Precautions taken to deal with these problems
___	___	Source of funding (what is covered)
___	___	Statement of participation from other individuals who are not co-investigators
___	___	Consent Form