

<b>UWO - HSREB</b>	<b>GUIDELINE</b>	<b>2-G-023</b>	<b>Page 1 of 1</b>
Effective date: August 1, 2002	<b>REQUIRED STANDARDS FOR INFORMED CONSENT FOR PLACEBO CONTROLLED TRIALS</b>		

**These standards have been approved by the HSREB for use in Multiple Sclerosis trials. Researchers wanting to utilize placebos in clinical trials for other diseases must make a case for the benefit/risk of a placebo trial of ‘their’ disease to overcome the current Tri-Council Policy Statement that essentially precludes a placebo trial if an ‘effective’ therapy is available.**

**Requirement 1.** In addition to the standard elements of the informed consent, the Letter of Information ‘preamble’ should clearly state why the trial is being done and why the particular subject is being recruited, both in terms of type of disease and because the subject is unwilling to use the recommended available medications.

*Additional phrase to be added to Letter of Information*

“There are established therapies for your disease, if you choose not to use any of these therapies you will then be eligible to participate in this clinical trial.”

**Requirement 2.** It is not necessary that the patient actually be treated with available agents first, but only that s/he be fully informed of available treatment options and given the opportunity to partake of those prior to being considered as a potential trial participant.

*Additional phrase to be added to Letter of Information*

“Please ask your study doctor to discuss these potential options with you before you agree to participate in this study.”

**Requirement 3.** The physician should actively recommend use of an available agent. The consent process should clearly reflect the investigator’s offer and the subject’s declination of available therapy. The patient should decline in writing the use of recommended available medication.

*Additional phrase to be added to Letter of Information*

“The following treatments are the current standard of care and have been shown to reduce symptoms and chance of a relapse by up to 30%. I would encourage you to consider using them before participating in this trial.”

*Additional phrase to be added to Consent Form sign-off*

“I have been informed of the current standards of care and have decided not to use them.”

**Requirement 4.** When ever possible consent would be strengthened by having a *neutral* party, rather than the study’s principal investigator or his/her staff involved in administering the informed consent. Investigators are strongly encouraged to make arrangements for this or discuss in their submission to the HSREB why this would not be feasible or advisable in this trial.

Adapted from:

Placebo-Controlled Clinical Trials in Multiple Sclerosis: Ethical Considerations  
Special Report - Lublin, F.D., Reingold, S.C. and the National Multiple Sclerosis Society (USA) on Placebo-Controlled Clinical Trials in MS: Annals of Neurology Vol. 49, No. 5, May 2001