Title of Protocol: _____ Site of Study: _____

TITLE OF PROTOCOL
INFORMED CONSENT FORM
MONTREAL NEUROLOGICAL INSTITUTE AND HOSPITAL
McConnell Brain Imaging Centre

GUIDELINES FOR PREPARATION

According to the Tri-Council Policy Statement – Ethical Conduct for Research Involving Humans, 1998, a human subject's involvement in research should be informed and voluntary. Investigators must provide subjects, in a language they understand,

also appear at the top of each page of the consent form. Also include the site of the study. The date on which
m has been prepared must appear in the bottom right hand corner of each page of the consent form.

2. REASON FOR THE STUDY

Include why the subject is invited to take part. The recommendation is made that the body of text in the consent form speak of the participant in the second person with the exception of the very last paragraph in which the subject signifies consent.

3. PROCEDURES

Give a fair description of the procedures in which the subject will be participating. The language of such description should be understandable to laypersons and clearly indicate experimental aspects of the study, the time commitment expected of the subject, and research techniques such as randomization and placebo use. <u>It is the investigator's responsibility</u> to anticipate which information may be important to the subject.

4. CONTRAINDICATIONS

The following are contraindications for a magnetic resonance study:

Pacemaker
Aneurysm Clip
Heart/Vascular Clip
Prosthetic Valve
Metal Prosthesis
Pregnancy
Claustrophobia
Metal fragments in body

9. WITHDRAWAL FROM THE STUDY

The right of the subject to withdraw from the study at any time without jeopardy of any kind, including ongoing and subsequent clinical care should be stated. It should also be indicated that any useful data obtained prior to withdrawal will be kept on record and used for research purposes and data analysis unless the subject provides written refusal to allow this. The subject should know that any secondary use of this data would be restricted to a research protocol in the same or related area of study and it would be require approval of the REB (Research Ethics Board).

10. INCIDENTAL FINDINGS

There should be an indication that the images are not routinely examined for abnormalities. However, should there be any incidental findings, they will be communicated to the subjects and upon their request, to their physicians

11. PROCEDURES OR TREATMENTS ALTERNATIVE TO A PROPOSED NEW THERAPY

To be described in all studies funded by USA granting agencies.

12. EFFECTS OF PARTICIPATION IN THIS STUDY

A clear statement whether Magnetic Resonance Imaging interferes with treatment.

13. SUBJECT'S AGREEMENT TO BE CONTACTED BY THE RESEARCH ETHICS BOARD

A statement should be included that the patient agrees to be contacted by a member of the Research Ethics Board, at the discretion of the board. The subject should also be made aware that the Research Ethics Board or quality Assurance Officers