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, enough information about the proposed study and their prospective role to enable them to decide whether to participate. The investigator should do this orally and personally before asking each subject to sign a consent form, a copy of which is given to the subject. In the case of invasive studies it is recommended that subjects be given a 24-hour period to think about their participation before signifying consent by signing.

To provide minimum information of informed consent ***(keeping as much as possible within a 2-page limit****), the consent form should contain the sections that follow.*

1. TITLE OF PROJECT

The title must also appear at the top of each page of the consent form. Also include the site of the study. The date on which the consent form 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.

- *Aneurysm Clip*
- *Heart/Vascular Clip*
- *Prosthetic Valve*
- *Metal Prosthesis*
-

7. CONFIDENTIAL NATURE OF THIS STUDY

Complete details regarding confidentiality of the prospective subjects and duration of retention of identifiable data must be given. It is necessary, in drug trials, to specify individuals or agencies that may have access to the data. You should disclose the need to retain the data if it is your intention to conduct follow-up studies.