

5. Letters of agreement and support from individuals or departments whose facilities are to be used:
- 5.a. MUHC/ MNH/ MNI departments or facilities (e.g., Director of professional Services (DPS), Neurological Services Operations Committee, etc)

5.b Regulatory Compliance

A clinical trial involving human subjects planned for conduct in Canada must comply with the regulations stipulated by the Food and Drugs Act including the Food and Drug Regulations, and be authorized by Health Canada (HC) via a No Objection Letter (NOL).

A clinical trial regulated by the US Food and Drug Administration (FDA), conducted at a non-US site must conform to the laws and regulations of the country in which the research is conducted (attestation). Refer to the US DHHS and FDA document entitled “Guidance for Industry: Acceptance of Foreign Clinical Studies”.

Research activities involving human subjects sponsored in whole or in part by the US federal government including the Public Health Service is conducted at the MUHC in compliance with a Federal Wide Assurance (FWA) for International Non-US Institutions.

For a clinical trial involving an investigational drug and/or biological, or a new indication for a marked product, was a Clinical Trial Application (CTA) filed with Health Canada (HC) seeking regulatory approval to conduct the study?

HealthCanada No Objection Letter must be appended.

- ☐ Yes, Health Canada reviewed the study and issued a “No Objection Letter” (NOL).
- ☐ Yes, but the Health Canada review determined the study does not require a CTA.

If NOL is not required append HC correspondence to justify.

☐ NO, Health Canada “NOL” is not required

6. Synopsis of scientific background of the project, how you will proceed with statistical analysis, and a very brief summary of goals/aims:
7. Drug studies protocol:
8. Detailed description of procedures to which patients, control and/or normal subjects will be subjected:

9. Does your protocol involve subjects who are part of a ‘special population’?
(Definition): Patients diagnosed with psychiatric, neurological or other medical disorders known potentially to affect competency, or juvenile subjects or mentally challenged subjects pursuant to the terms of Article 21 of the Quebec Civil Code.)
 - (a) If yes, how will you assess the competence of subjects to consent to being involved in the study?¹
 - (b) If yes, what measures have you taken to ensure the immediate availability of medical assistance, if necessary, during the participation of subjects in the protocol?
 - (c) If yes, please consult the Guidelines for Protocols Involving Special Populations.
10. Outline any anticipated risks, e.g., medical, psychological, privacy and confidentiality, and the specific measures contemplated to ensure that any potential risk to the subject is being avoided.
11. English and French consent documents bearing version dates. Please indicate whether the granting agency specifically requires REB approval of the consent documents.
12. Proposed number of subjects for the entire duration of the study (please specify the number of patients, controls and/or normal subjects) and estimated duration of the study:
 - (a) Number of subjects to be studied in the first year:
13. Granting agency to which project is to be submitted:
 (Please provide also the grant number & McGill Fund # if known)
14. If not being submitted to a granting agency, information regarding source of funding:
15. Has the project been peer-reviewed (indicate yes ☐ or no ☐);
16. Source and method of recruitment of subjects:
17. Copy of any advertisement (English & French) in recruiting volunteers for the study:
18. If the protocol arises from a grant submission, please attach one final copy of the grant submission.

¹Assessment and verification of subject's competence:

- a) Does the subject have factual understanding of the protocol as described in the consent document?
- b) Does the subject have full cognizance of risks and benefits of participation?
- c) Cite and attach any additional sources of information the subject may be given:
- d) Is the subject able to understand [manipulate rationally] the terms of the consent s/he is signing and to collaborate safely in the protocol in view of her/his medical condition(s):
- e) Is the subject aware that experimentation is proceeding in a research facility and not a primarily medical care setting:

19. For resubmissions only, please clearly indicate all changes made since the original submission. Whenever submitting protocol amendments or revisions, please provide a brief statement indicating the significance, if any, of the changes made and whether the consent documents need to reflect these changes.
20. Signature of principal investigator(s) _____

Date: _____