



**INDEPENDENT REVIEW BOARD APPROVAL FORM**

By Electronic Mail to [diana.salazarospina@mcgill.ca](mailto:diana.salazarospina@mcgill.ca)

July 15, 2014

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**RE: Clinical Study Protocol CTN-273: Understanding and Optimizing Brain Health in HIV Now (Positive Brain Health Now)**

The following documents were reviewed and acknowledged by the Independent Review Board Vice Chair in compliance with normative documents governing research with humans:

- Communication from Sponsor dated July 14, 2014
- Informed Consent Documentation – Main, Version 2.0, Template, English and French versions, dated June 30, 2014
- Informed Consent Documentation – Optional DNA Research, Version 2.0, Template, English and French versions, dated June 30, 2014
- Informed Consent Documentation – Cognitive Training Sub-Study, Version 2.0, Template, English and French versions, dated June 30, 2014
- Informed Consent Documentation – Neuropsychological Evaluation Sub-Study, Version 1.0, Template, English and French versions, dated June 30, 2014
- ‘CIHR awards \$2,492,705 to study how to improve brain health in people living with HIV’ – Cohort Information Sheet, English and French versions, undated, submitted July 14, 2014.

Please find below the status of approval for the following documents:

Informed Consent Documentation – Main  
Version 2.0  
Template  
(English and French versions, dated June 30, 2014)

- Unconditionally Approved*
- Conditionally Approved*
- Deferred*
- Disapproved*

Informed Consent Documentation – Optional DNA Research  
Version 2.0  
Template  
(English and French versions, dated June 30, 2014)

- Unconditionally Approved*
- Conditionally Approved*
- Deferred*
- Disapproved*

Informed Consent Documentation – Cognitive Training Sub-Study  
Version 2.0  
Template  
(English and French versions, dated June 30, 2014)

- Unconditionally Approved*
- Conditionally Approved*
- Deferred*
- Disapproved*

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Informed Consent Documentation – Neuropsychological Evaluation  
Sub-Study, Version 1.0  
Template  
(English and French versions, dated June 30, 2014)

*Unconditionally Approved*  
 *Conditionally Approved*  
 *Deferred*  
 *Disapproved*

'CIHR awards \$2,492,705 to study how to improve brain health  
in people living with HIV' – Cohort Information Sheet  
(English and French versions, undated, submitted July 14, 2014)

*Unconditionally Approved*  
 *Conditionally Approved*  
 *Deferred*  
 *Disapproved*

The following is a **note** from the Independent Review Board Vice Chair:

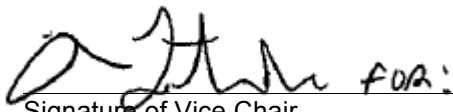
- The Communication from Sponsor dated July 14, 2014 satisfies the query with consequence placed on the Questionnaires by the Independent Review Board in its Approval Form dated June 25, 2014.

#### **ACTION TO BE TAKEN**

- Clinical Study Protocol CTN-273, Version 3.0 (dated April 1, 2014) is now unconditionally approved by the Independent Review Board. However, commencement of this Study by Investigators under the jurisdiction of this Independent Review Board is not granted by this Approval Form. Approval to commence the Study at each investigational Site will be granted upon issuance of the following documents by the Independent Review Board:
  - Completed Principal Investigator and Site Submission Form;
  - Site-specific versions of the unconditionally-approved Informed Consent Documentation;
  - Curriculum Vitae and Current Medical License for each Investigator and Sub-investigator(s);
  - Copy of the Investigator's signed Clinical Trial Agreement with the Sponsor;
  - Study Budget or information regarding Study payments to Investigator.

Should you have any questions or require clarification of any issues, please do not hesitate to contact us.

Thank you.



Signature of Vice Chair  
Independent Review Board

Jacqueline Brunning, PhD  
Name of Vice Chair  
Independent Review Board

This approval is valid until June 23, 2015, the date of Annual Review.