

INDEPENDENT REVIEW BOARD APPROVAL FORM

By Electronic Mail to diana.salazarospina@mcgill.ca

July 25, 2014

Dr. Réjean Thomas
 c/o Diana Salazar
 McGill University Health Centre
 Montreal Chest Institute
 3650 St-Urbain
 Montréal, Québec
 H2X 2P4

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:

- Communications (2) from Sponsor dated July 23, 2014
- Principal Investigator and Site Submission Form dated May 26, 2014 (Site-specific: Dr. Réjean Thomas)
- Informed Consent Documentation – Main, Version 2.0, English and French versions, dated July 21, 2014 (Site-specific: Dr. Réjean Thomas)
- Informed Consent Documentation – Optional DNA Research, Version 2.0, English and French versions, dated July 21, 2014 (Site-specific: Dr. Réjean Thomas)
- Informed Consent Documentation – Cognitive Training Sub-Study, Version 2.0, English and French versions, dated July 21, 2014 (Site-specific: Dr. Réjean Thomas)
- Informed Consent Documentation – Neuropsychological Evaluation Sub-Study, Version 1.0, English and French versions, dated July 21, 2014 (Site-specific: Dr. Réjean Thomas)
- Study Advertisement ‘How does HIV affect your brain?’ – Poster, English and French versions, dated July 21, 2014 (Site-specific: Dr. Réjean Thomas)
- ‘Positive Brain Health Now: Information Sheet’, Version 4, English and French versions, dated June 3, 2014 (Site-specific: Dr. Réjean Thomas)
- Study Budget, undated, submitted July 23, 2014
- Clinical Trial Agreement signed on June 2, 2014
- Curriculum Vitae dated September 26, 2013 and Current Medical License information for Dr. Réjean Thomas
- Curriculum Vitae dated September 12, 2012 and Current Medical License for Dr. Benoît Trottier
- Communication dated July 24, 2012 regarding the Health Canada inspection at the Site.

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

Informed Consent Documentation – Main
 Version 2.0
 Site-specific: Dr. Réjean Thomas
 (English and French versions, dated July 21, 2014)

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

Informed Consent Documentation – Optional DNA Research Version 2.0 Site-specific: Dr. Réjean Thomas (English and French versions, dated July 21, 2014)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<i>Unconditionally Approved</i> <i>Conditionally Approved</i> <i>Deferred</i> <i>Disapproved</i>
Informed Consent Documentation – Cognitive Training Sub-Study Version 2.0 Site-specific: Dr. Réjean Thomas (English and French versions, dated July 21, 2014)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<i>Unconditionally Approved</i> <i>Conditionally Approved</i> <i>Deferred</i> <i>Disapproved</i>
Informed Consent Documentation – Neuropsychological Evaluation Sub-Study, Version 1.0 Site-specific: Dr. Réjean Thomas (English and French versions, dated July 21, 2014)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<i>Unconditionally Approved</i> <i>Conditionally Approved</i> <i>Deferred</i> <i>Disapproved</i>
Study Advertisement ‘How does HIV affect your brain?’ – Poster Site-specific: Dr. Réjean Thomas (English and French versions, dated July 21, 2014)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<i>Unconditionally Approved</i> <i>Conditionally Approved</i> <i>Deferred</i> <i>Disapproved</i>
‘Positive Brain Health Now: Information Sheet’ Version 4.0 Site-specific: Dr. Réjean Thomas (English and French versions, dated July 21, 2014)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<i>Unconditionally Approved</i> <i>Conditionally Approved</i> <i>Deferred</i> <i>Disapproved</i>
Study Budget (undated, submitted July 23, 2014)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<i>Unconditionally Approved</i> <i>Conditionally Approved</i> <i>Deferred</i> <i>Disapproved</i>

Principal Investigator and Site Submission Form, Curricula Vitae and Current Medical Licenses

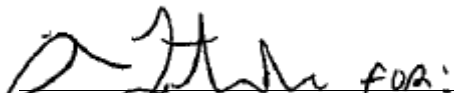
- Dr. Réjean Thomas is unconditionally approved as a Principal Investigator for the above-referenced Study, along with the following Sub-investigator: Dr. Benoît Trottier.

NOTES

- As the Clinical Study Protocol CTN-273 (Version 3.0) dated April 1, 2014, Informed Consent Documentation, Study Budget, Investigator and Sub-investigator have been approved, the above-referenced Study may now commence at the Site of Dr. Réjean Thomas;
- All unexpected and related Serious Adverse Events that are experienced by Participants in this Study must be reported to the Independent Review Board within 5 business days. Should these Serious Adverse Events occur, please alert us by completing the attached form and returning it to us by facsimile at (514) 336-1142. In the event that a more complete report may be needed, you will be notified. Any Unanticipated Events must be reported in a timely manner, in accordance with Veritas IRB Reporting Policies and Procedures (see attached);

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

Thank you.

A handwritten signature in black ink, appearing to read 'J. Brunning FOR:'. The signature is written over a horizontal line.

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.