



INDEPENDENT REVIEW BOARD APPROVAL FORM

By Electronic Mail to diana.salazarospina@mcgill.ca

July 25, 2014

Dr. Graham H.R. Smith
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 April 1, 2014 (Site-specific: Dr. Graham H.R. Smith)
- Informed Consent Documentation – Main, Version 2.0, English version, dated July 21, 2014 (Site-specific: Dr. Graham H.R. Smith)
- Informed Consent Documentation – Optional DNA Research, Version 2.0, English version, dated July 21, 2014 (Site-specific: Dr. Graham H.R. Smith)
- Informed Consent Documentation – Cognitive Training Sub-Study, Version 2.0, English version, dated July 21, 2014 (Site-specific: Dr. Graham H.R. Smith)
- Study Advertisement ‘How does HIV affect your brain?’ – Poster, English version, dated July 21, 2014 (Site-specific: Dr. Graham H.R. Smith)
- ‘Positive Brain Health Now: Information Sheet’, Version 4.0, English version, dated June 3, 2014 (Site-specific: Dr. Graham H.R. Smith)
- Study Budget, undated, submitted July 23, 2014
- Clinical Trial Agreement signed on July 12, 2014
- Curriculum Vitae dated November 26, 2013 and Current Medical License for Dr. Graham H.R. Smith
- Curriculum Vitae dated November 26, 2013 and Current Medical License for Dr. Jason Brunetta
- Curriculum Vitae dated November 26, 2013 and Current Medical License for Dr. Mona R. Loutfy
- Communication from Health Canada dated January 17, 2014 regarding a Site inspection.

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

Informed Consent Documentation – Main
Version 2.0
Site-specific: Dr. Graham H.R. Smith
(English version, dated July 21, 2014)

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

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Informed Consent Documentation – Optional DNA Research Version 2.0 Site-specific: Dr. Graham H.R. Smith (English version, 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. Graham H.R. Smith (English version, 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. Graham H.R. Smith (English version, 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. Graham H.R. Smith (English version, dated June 3, 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

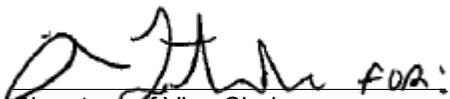
- Dr. Graham H.R. Smith is unconditionally approved as a Principal Investigator for the above-referenced Study, along with the following Sub-investigators: Dr. Jason Brunetta and Dr. Mona R. Loutfy.

NOTES

- As the Clinical Study Protocol CTN-273 (Version 3.0) dated April 1, 2014, Informed Consent Documentation, Study Budget, Investigator and Sub-investigators have been approved, the above-referenced Study may now commence at the Site of Dr. Graham H.R. Smith;
- 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:', 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.