



Research Ethics Board (REB)

The Research Ethics Board for The Hospital for Sick Children is organized and operates according to the principles and practices outlined in the Tri-Council Policy Statement, the ICH Harmonized Tripartite Guidelines: Good Clinical Practice, and Division 5 and the Medical Devices Regulations of the Food and Drug Act as well as the Natural Health Products Regulations of Health Canada. This signed document is in lieu of the Health Canada Research Ethics Board Attestation Form.

Approval & Terms of Agreement

Investigators: Dr. Lars Grosse-Wortmann, P.Kantor, R.Chaturvedi, H.Holtby, S.Yoo

Study Title: Detection of Graft Rejection in Heart Transplant Recipients by Magnetic Resonance Imaging

REB File number: 1000013662 **Level of Continuing Review:** II D

Protocol Version Date: May 12 2009

Consent & Assent Form Version Date(s): Participant Consent for HTx Rejection – June 22 2009, Parent Consent for HTx Rejection – June 22 2009, Assent for HTx Rejection – May 13 2009, Participant Consent for Controls – May 13 2009, Parent Consent for Controls – May 13 2009, Assent for Controls – May 13 2009

Investigator's Brochure Version Date: N/A

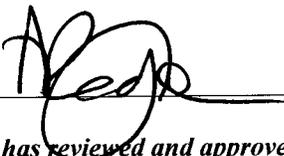
Other Approved Recruitment Document Dates: N/A

I agree to carry out the proposed research involving human subjects in accordance with the above-noted guidelines and regulations (as applicable) and using only the REB-approved study protocol and consent/assent form(s). I shall notify the division/department head and the REB prior to implementing any amendments in the protocol and consent/assent forms and of any deviations or any changes in study activity. I shall also notify the REB of any unexpected adverse events as per REB guidelines. As applicable, I certify that the research contract and corresponding protocol are consistent and will inform the contract manager of any protocol amendments as required.

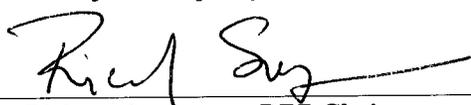
I agree that, in accordance with the Personal Health Information Protection Act of Ontario, I am responsible for adhering to all conditions and restrictions imposed by the REB governing the use, security, disclosure, return and disposal of the research subjects' personal health information. I am also responsible for reporting immediately any privacy breaches to the REB Chair and to Janice Campbell, the Sick Kids privacy officer. I will ensure that the personal health information is used, only as necessary, to fulfill the specific research objectives and related research questions described in this application and approved by the REB.

Signature of Principal Investigator  **DATE** 2009.6.24

I approve of this research protocol, agree to share responsibility for its proper conduct, and will ensure that the REB is notified of concerns, as appropriate.

Signature of Division/Department Head  **DATE** 27/june 09

The REB of the Hospital for Sick Children has reviewed and approved the above-named research study.


Mr. Richard Sugarman, REB Chair
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DATE OF APPROVAL July 3, 2009 **EXPIRY DATE** July 2010