May 14, 2012

PROJECT NUMBER: 12-089

PROJECT TITLE: Group versus Individual Urotherapy for Children with Non-Neurogenic Lower Urinary Tract Dysfunction

PRINCIPAL INVESTIGATOR: Natasha Brownrigg

This will acknowledge receipt of your letter dated May 4, 2012 which enclosed revised copies of the Information/Consent Form, Assent Form, Application Form and the Budget along with response to the additional queries of the Board for the above-named study. These issues were raised by the Research Ethics Board at their meeting held on February 21, 2012. Based on this additional information, we wish to advise your study has been given final approval from the full REB. The submission, Study Protocol version 1.2 dated April 4, 2012 including the Information/Consent Form and the Assent Form both versions dated April 4, 2012 together with Individual Urotherapy Checklist; Helping Your Child Develop Healthy Bladder Habits Booklet; Curriculum for Group Teaching Session; Vancouver NULTD/DES Questionnaire; PinQ Quality of Life Questionnaire and Demographic Questionnaire were found to be acceptable on both ethical and scientific grounds. The Board also acknowledges Clinical Trial Registration # NCT01570673. Please note attached you will find the Information/Consent Form and the Assent Form with the REB approval affixed; all consent forms/assent forms used in this study must be copies of the attached materials.

We are pleased to issue final approval for the above-named study for a period of 12 months from the date of the REB meeting on February 21, 2012. Continuation beyond that date will require further review and renewal of REB approval. Any changes or revisions to the original submission must be submitted on an REB amendment form for review and approval by the Research Ethics Board.

The Hamilton Health Sciences/McMaster Health Sciences Research Ethics Board operates in compliance with and is constituted in accordance with the requirements of: The Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans; The International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations.

PLEASE QUOTE THE ABOVE-REFERENCE PROJECT NUMBER ON ALL FUTURE CORRESPONDENCE

Sincerely,

Suzette Salama PhD,
Chair, Research Ethics Board