Centre universitaire de santé McGill

McGill University Health Centre

Centre d'éthique appliquée
Centre for Applied Ethics

Revised July 21, 2015

Dr. Giada Sebastiani
MUHC – MCI
Room J8.03

Re: "Non-invasive Diagnosis of Non-alcoholic Steatohepatitis in Liver Transplant Recipients: A Prospective, Longitudinal Study Employing Serum Cytokeratin 18 and Transient Elastography (Fibroscan)"

Dear Dr. Sebastiani,

We are writing in response to your re-submission providing clarifications and revised documents required by the MUHC-REB Clinical Trials II Panel B for the study referenced above. The study was assigned Study Code 15-002-MUHC as the reference when discussing the study. At the MUHC, sponsored research activities that require US federal assurance are conducted under Federal Wide Assurance (FWA) 00000840.

We are pleased to inform you that the study received Full Board review at the convened meeting of the MUHC-REB on April 15, 2015 and was found to meet the ethical standards for conduct at the MUHC. The information was entered accordingly in the minutes of the meeting.

Approval for the study was provided on May 25, 2015 and includes the:

Revised Research Protocol (Version 1.2 May 20, 2015);
Revised Information and Consent Document (Version 1.2 May 7, 2015) in French and English;
Screening Visit Questionnaire (December 29, 2014) in French and English;
Study Visit Questionnaire (December 29, 2014) in French andEnglish.

All research with human subjects requires ongoing REB oversight and the approval will be in effect until **May 24, 2016**. Prior to the expiration of ethics approval, it is your responsibility to submit to the REB either an "Application for Continuing Review" when the study is ongoing, or a "Study Completion Report" if the research has been completed.

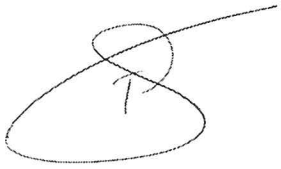
The MUHC Research Ethics Boards (REBs) work under the published guidelines of the *"Tri-Council Policy Statement 2"*, and the *"Plan d'action ministériel en éthique de la recherche et en intégrité scientifique"*, and in compliance with the *"Food and Drugs Act"*, including the *"Food and Drug Regulations"*, the *"Medical Devices Regulations"*, and the *Natural Health Products Regulations*, and act in conformity with standards set forth in the *(US) "Code of Federal Regulations"* governing human subjects research, and in a manner consistent with internationally accepted principles of good clinical practice.

You must report to the REB promptly without delay should a modification to the research be proposed, and without delay if an unanticipated problem occurs before the next required review. Regulations do not permit you to modify conduct of the study prior to ethics approval for a study amendment; except where urgent action is required to eliminate an apparent immediate hazard to a study subject or other person.

It is important to note you may initiate the study only after all required reviews have been completed and all decisions are favorable. At that time you will receive MUHC Authorization to conduct the study in correspondence issued by the Research Institute of the MUHC.

We trust this will prove satisfactory to you.

Sincerely,



Thomas Maniatis, MD, CM, MSc (Bioethics), FACP, FRCPC
Co-Chair,
MUHC-REB

Cc: 15-002-MUHC
Danielle Ricard