Centre universitaire de santé McGill | McGill University Health Centre

2018-06-14

Dr. Giada Sebastiani
1001 Decarie Boulevard
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Montreal, Quebec
H4A 3J1

c/o: Maria Osikowicz

email: maria.osikowicz@muhc.mcgill.ca

Re: Final REB Approval of a New Research Project (FLIPCOS / 2019-4584)

"Determining prevalence and predictors of non-alcoholic fatty liver disease in patients with polycystic ovary syndrome: The Fatty LIver in polycystic ovary syndrome (FLIPCOS) study'

MUHC REB Co-Chair for the Clinical trials 2 (CT2) Panel: Dr. Thomas Maniatis

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Dear Dr. Sebastiani,

Thank you for submitting your responses and corrections for the research project indicated above, as requested by the McGill University Health Centre (MUHC) Research Ethics Board (REB).

The MUHC REB, more precisely its CT2 Panel provided conditional approval for the research project after a delegated review provided by its member(s).

On 2018-06-14, a delegated review of your responses and corrections was provided by a member of the MUHC REB. The research project was found to meet scientific and ethical standards for conduct at the MUHC.

The following documents were approved or acknowledged by the MUHC REB:

- Initial Submission Form (F11-30562)
- REB Conditions & PI Responses Form(s) (F20-31335, F20-32564)
- Research Protocol (Version 1.0 2018-04-13)
- Information & Consent Form (Version 1.2 2018-06-08) in French and English
- Approval of the Department / Division Head (2018-04-13)
- CRF Screening Visit Questionnaire (2018-06-08)

This will be reported to the MUHC REB and will be entered accordingly into the minutes of the next CT2 Panel meeting. Please be advised that you may only initiate the study after all required reviews and decisions are received and documented and you have received the MUHC authorization letter.

The approval of the research project is valid until 2019-06-13.

All research involving human subjects requires review at recurring intervals. To comply with the regulation for continuing review of at least once per year, it is the responsibility of the investigator to submit an *Annual Renewal Submission Form* (F9) to the REB prior to expiry. Please be advised that should be protocol reach its expiry before a Continuing review has been submitted, the data collected after the expiry date may not be considered valid. However, should the research conclude for any reason prior to approval expiry, you are required to submit a *Completion (End of Study) Report* (F10) to the board once the data analysis is complete to give an account of the study findings and publication status.

Furthermore, should any revision to the project or other development occur prior to the next continuing review, you must advise the REB without delay. Regulation does not permit initiation of a proposed study modification prior to its approval by the REB.

The MUHC REB is registered and works under the published guidelines of the *Tri-Council Policy Statement 2*, in compliance with the *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique* (MSSS, 1998) and the *Food and Drugs Act* (2001.06.07), acting in conformity with standards set forth in the (US) *Code of Federal Regulations* governing human subjects research and functioning in a manner consistent with internationally accepted principles of good clinical practice.

We trust this will prove satisfactory to you. Thank you for your consideration in this matter.

Best Regards,

Sheldon Levy

MUHC REB Coordinator
for MUHC REB Co-chair mentioned above