

Dr. LEGROS Benjamin
Department of Neurology
Hôpital Erasme
Route de Lennik 808
B-1070 Bruxelles

Brussels, April 23, 2013

Comité d'Ethique
hospitalo-facultaire
Erasme - ULB
(021 / 406)

Dear Dr. LEGROS Benjamin,

Please find further on the answer of the Ethics Committee concerning the amendment **A2013/057**.

ETHICS COMMITTEE APPROVAL

We, undersigned,
Chairman & Secretary of

Pr. C. MELOT & Mr. G. NISSET
Ethics Committee Erasme Hospital
808, route de Lennik
B-1070 Brussels, Belgium
N° of agreement by "Ordre des Médecins": OM021

confirm that during the meeting held on 23/04/2013 (dd/mm/yyyy), the Ethics Committee renewed its approval of the ongoing study after reviewing the following documents related with the clinical trial *An international pilot study of an Internet-based platform to run epilepsy trials.*» (EudraCT / CCB: B40620109160; Our Ref. **P2010/231**).


- Amendment (Poursuite d'inclusion de patients Erasme dans ce registre international maintenant validé et consentement obtenu par non opposition sur base d'un document d'information aux patients des objectifs et finalités du registre.)
- Patient information sheet in French: Version dated November 14, 2012

Following document, included in the submission file, have been also reviewed:

- Cover letter dated February 08, 2013
- Summary

The list of the names and qualifications of the members of the Ethics Committee as well as the list of the members absent and present at the meeting are added in appendix.

We hereby confirm that this Ethics Committee is organized and operates according to ICH GCP and the applicable local laws and regulations.



Mr G. NISSET
Secretary



Pr C. MELOT
Chairman

CC: Dr Peter BERGIN, , Auckland City Hospital; - , Auckland, New Zealand

List of Members present at the meeting of 23/04/2013 (dd/mm/yyyy)

Comité d'Ethique
hospitalo-facultaire
Erasmus - ULB
(021 / 406)

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Président :

Pr C. MELOT

Vice-Présidents :

Pr S. GOLDMAN

Pr M. REMMELINK

Pr M. MANTO

Dr J.L. VACHIERY

Secrétaire :

Mr G. NISSET

Past President:

Pr A. HERCHUELZ

- = present
- = absent
- E = excused

- Pr C. MELOT, Emergency doctor, MD, PhD, Male, Scientist, Affiliated
- Pr S. GOLDMAN, Neurologist, MD, PhD, Male, Scientist, Affiliated
- E Pr M. REMMELINK, Pathologist, MD, PhD, Female, Scientist, Affiliated
- Pr M. MANTO, Neurologist, MD, PhD, Male, Scientist, Affiliated
- E Dr J.-L. VACHIERY, Cardiologist, MD, Male, Scientist, Affiliated
- Mr G. NISSET, Ethics Committee Secretary, BSc, PhD, Male, Scientist, Affiliated
- Pr A. HERCHUELZ, Pharmacologist, MD, PhD, Male, Scientist, Affiliated
- E Pr S. ALEXANDER, Gynecologist, MD, PhD, Female, Scientist, Affiliated
- E Dr J. BERRE, Intensivist, MD, Male, Scientist, Affiliated
- Dr J.-C. BIER, Neurologist, MD, Male, Scientist, Affiliated
- E Pr J.-M. BOEYNAEMS, Biologist, MD, PhD, Male, Scientist, Affiliated
- Dr S. DE BREUCKER, Geriatriest, MD, Female, Scientist, Affiliated
- E Dr E. DEMANET, General Practitioner, MD, Male, Scientist, Affiliated
- Dr P. DEMETTER, Pathologist, MD, PhD, Male, Scientist, Affiliated
- Dr F. FELGUEROSO-BUENO, General Practitioner, MD, Male, Scientist, Affiliated
- Mr P. FISCHBACH, Psychologist, BSc, Male, Scientist, Affiliated
- E Pr V. FONTAINE, Microbiologist, PhD, Female, Scientist, Affiliated
- Me B. FONTEYN, Lawyer, Male, Non Scientist, Non Affiliated
- Mme. N. GAMMAR, Assistant Nursing Director, Nurse, Female, Scientist, Affiliated
- Dr R. IMBERT, Gynecologist, MD, Male, Scientist, Affiliated
- Me A. KAHN, Lawyer, Female, Non Scientist, Non Affiliated
- Pr H. LOUIS, Gastroenterologist, MD, PhD, Male, Scientist, Affiliated
- Dr R. MARECHAL, Gastroenterologist, MD, PhD, Male, Scientist, Affiliated
- E Pr M. MBIYANGANDU KADIATA, Chemist, PhD, Male, Scientist, Affiliated
- E Mr M. MAYER, Moral Counsel, BSc, PhD, Male, Non Scientist, Affiliated
- Dr J. ROUBY, General Practitioner, MD, Male, Scientist, Non Affiliated
- Mme C. SAUVAGE, Physiotherapist, BSc, Female, Scientist, Affiliated
- Mr R. SURIN, Nurse, Male, Scientist, Affiliated
- Mme B. WAUTHION, Lay people, Female, Non Scientist, Affiliated

Notification of conflict of interest for some clinical research projects evaluated during the present meeting:
NONE.

Edited April 23, 2013

