



Pr. Marc JAYANKURA
Service d'Orthopédie - Traumatologie

Brussels, August 23, 2019

Dear Pr. JAYANKURA,

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

Please find further on the answer of the Ethics Committee concerning the below mentioned study.

ETHICS COMMITTEE APPROVAL

We, undersigned, "Board Members" of

Ethics Committee Erasme Hospital
808, route de Lennik
B-1070 Brussels, Belgium

Secrétariat
T 02 555 37 07
02 555 37 11
F 02 555 46 20

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confirm that the documents submitted for approval were initially examined on the meeting held on 06/08/2019 (dd/mm/yyyy).

After examination of the answers to the received the 13/08/2019, the Ethics Committee gave its agreement on 19/08/2019 to the following documents:

- Protocol (References : P2019/390) entitled: "*Comparaison entre la voie antérieure directe mini-invasive avec support de jambe et la voie postérolatérale pour le traitement par hémiprotèse des fractures déplacées intracapsulaires du col fémoral chez les patients âgés.*" (Your Ref.: Included in the Ethic's Committee Application Form)

The following document(s), included in the submission file, has/have also been reviewed:

- Ethics Committees Application form signed the 23/07/2019
- Research Data Table

We also confirm the suitability of the local investigator and his team and the quality of local facilities.

This agreement is valid from 19/08/2019 till 30/09/2019.

The Committee reminds the investigator of his personal responsibility for this project. We consider your responsibility, in accordance with the recommendations of ICH GCP, that annual trial status and end trial results will be transmitted to the Committee.

The list of the names and qualifications of the members of the Ethics Committee present at the meeting is added in appendix.

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

Pr J.-M. BOEYNAEMS
Chairman





List of Members present at the meeting of 06/08/2019 (dd/mm/yyyy)

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

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Président

Pr J.-M. BOEYNAEMS

Vice-Présidents

Pr S. GOLDMAN

Pr H. LOUIS

Consultants

Pr B. BYL

Pr A. DEMOLS

Pr F. VERMEULEN

Pr Y. HENNEQUIN

Mr G. NISSET

■ = present

□ = absent

E = excused

- Pr J.-M. BOEYNAEMS, Biologist, MD, PhD, Male, Scientist, Affiliated
- E Pr S. GOLDMAN, Neurologist, MD, PhD, Male, Scientist, Affiliated
- E Pr H. LOUIS, Gastroenterologist, MD, PhD, Male, Scientist, Affiliated
- Mrs B. ABOUZE, Lawyer, Female, Non Scientist, Affiliated
- Mrs M. ALVAREZ VILLAMANDOS, Nurse, Female, Non-Scientist, Affiliated
- E Mr S. BAUDRY, Physiologist, Bsc, PhD, Male, Scientist, Affiliated
- E Mrs L. BENAMMAR, Hospital Pharmacist, Female, Scientist, Affiliated
- Dr J.-C. BIER, Neurologist, MD, Male, Scientist, Affiliated
- Mr. A. COUNET, Economist, Male, Non Scientist, Member of a Patients Association
- E Dr E. DEMANET, General Practitioner, MD, Male, Scientist, Non Affiliated
- Mrs L. DIDENS, Nurse, Female, Non-Scientist, Affiliated
- Dr F. FELGUEROSO-BUENO, General Practitioner, MD, Male, Scientist, Affiliated
- Pr V. FONTAINE, Microbiologist, PhD, Female, Scientist, Affiliated
- E Me B. FONTEYN, Lawyer, Male, Non Scientist, Non Affiliated
- Dr J. GROSSWASSER, Paediatricist, MD, PhD, Male, Scientist, Non Affiliated
- Dr A. JOOSTEN, Anesthetist, MD, Male, Scientist, Affiliated
- Pr I. LANGER Pharmacologist, PharmaD, PhD, Female, Scientist, Affiliated
- Dr V. LESAGE, Geriatist, MD, Female, Scientist, Affiliated
- E Pr G. LOAS, Psychiatrist, MD, PhD, Male, Scientist, Affiliated
- E Me Th. LOCOGE, Lawyer, Female, Non Scientist, Non Affiliated
- E Mr M. MAYER, Moral Counsel, BSc, PhD, Male, Non Scientist, Affiliated
- E Pr Ph. PEIGNEUX, Psychologist, BSc, PhD, Male, Scientist, Non Affiliated
- Mme A. PETIAU, Psychologist, Female, Scientist, Affiliated
- Mr. C. PLOMTEUX, Male, Non Scientist, Representative Healthy Volunteers, Non Affiliated
- Dr J. ROUBY, General Practitioner, MD, Male, Scientist, Non Affiliated
- E Pr F. ROUFOSSE, Internist, MD, PhD, Female, Scientist, Affiliated
- E Mme C. SAUVAGE, Physiotherapist, BSc, PhD, Female, Scientist, Affiliated
- E Mrs S. SCHOLTES, Hospital Pharmacist, Female, Scientist, Affiliated
- E Pr Ph. VAN DE BORNE, Cardiologist, MD PhD, Male, Scientist, Affiliated
- E Pr J.-L. VACHIER, Cardiologist, MD, Male, Scientist, Affiliated
- Pr C. VERHOEVEN, Biostatistician, PhD, Female, Scientist, Affiliated

Next meeting: August 20, 2019

Chairman: Prof. Jean-Marie Boeynaems

Notification of conflict of interest for some clinical research projects evaluated during the present meeting: Dr Joosten
(P2019/347)

EC SOP: -

Edited August 06, 2019

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