**Committee for the Protection of Persons**

**Est-II**

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The President, Besançon, 17 March 2020

**CHU DE MONTPELLIER**

**Ms. Odile BARDET
 39 Avenue Charles Flahault**

**34295 MONTPELLIER**

JMC/KJ

**CNRIPH protocol reference : 19.11.29.43226**

**Reference: “Assessment of the efficacy of a fatigue management therapy in schizophrenia: study protocol for a randomized, controlled multi-centric study” – ENERGY study**

(reference to be included imperatively in all correspondence)

Copy: **HOPITAL LA COLOMBIERE**

**Professeur Delphine CAPDEVIELLE**

**Service Universitaire de Psychiatrie Adulte**

**39 Avenue Charles Flahault
34295 MONTPELLIER Cedex 5**

Ms.,

The Committee, at its session on Monday 20 January 2020 examined the study (cat.2 HPS) entitled :

“**Assessment of the efficacy of a fatigue management therapy in schizophrenia: study protocol for a randomized, controlled multi-centric study” - ENERGY Study.**

By your answers of 06/03/20: the modifications made to the protocol answer all the questions raised by the CPP during the session.

The CPP Est-II operates in accordance with Good Clinical Practice (ICH-GCP).

Given the initial letter requesting an opinion dated 29/11/19, the opinion request form and the additional document dated and signed on 29/11/19, the protocol and its summary (version 1.0 of 27/11/19), the information note intended for "trusted persons/curators/guardians" and the information note intended for "patients" (version 2.0 of 04/03/20), the "Justification of human, material and technical means" dated and signed on 29/11/19, the investigator list (version 1 of 29/11/19) with the corresponding CVs including the CV of Pr Capdevielle - Hôpital de la Colombière in Montpellier, the fifteen questionnaires under study provided and the "Lloyd's" insurance certificate dated and signed on 29/11/19, the committee unanimously gives a **FAVOURABLE NOTICE.**

**MEMBER ATTENDANCE**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **CATEGORY** | **TITULARS** | **FUNCTION** | **PRESENT** | **ADDITIONS** | **FUNCTION** | **PRESENT** |
| I. BIOMEDICAL RESEARCH | Dr M.B VALNET RABIER | Hospital Practitioner CHRU Besançon | X | Dr C. GUILLERMET- FROMENTIN | Pediatrician CHRU of Besançon | X |
| Pr J.M. CHALOPIN (President) | Nephrologist Consultant CHRU Besançon | X | Ms. L. VETTORETTI | Clinical Research Engineer CHRU Besançon | X |
| Pr E. MONNET | Medical Epidemiologist CHRU Besançon |  | Dr G. BESH | PH Anesthesiologist CHRU of Besançon |  |
| II. GENERAL MEDICINE |  |  |  |  |  |  |
| III. PHARMACIST | Ms. S. PERRIN | Hospital Practitioner CHRU of Besançon | X | Ms. P. DEMOLY- POURET | Hospital Practitioner GCS Bavilliers Pharmacy | X |
| IV. NURSE | Ms. K. MOUGEY- CHEMETT | Nurse Direction of Care – CHRU of Besançon | X |  |  |  |
| V. ETHICS | Mr A. DIRAND | Doctoral student in philosophy at the UFC | X |  |  |  |
| VI. SOCIAL | Ms. A. BOURGE | Social worker CHBM | X |  |  |  |
| VII. PSYCHOLOGY | Ms. M. BONNET LLOMPART | Senior Lecturer in Clinical Psychology at the UFR SLHS in Besançon, France. | X | Ms. L. BARTHOD | Clinical Psychologist Clinic CHRU of Besançon |  |
| VIII. LEGAL EXPERT |  |  |  |  |  |  |
| Ms. S. DEPIERRE (Vice-President) | Head of Regulatory Unit DRCI CHRU Besancon |  | Mr A. CHAUSSY | CPAM of DOUBS Legal and Litigation Department |  |
| IX. REPRESENTATIVES OF APPROVED ASSOCIATIONS OF PATIENTS OR USERS OF THE HEALTH SYSTEM | Mr M. COTTINY | Director of Grand Besançon Habitat and UDAF 25 |  | Ms. B. LANQUETIN | Retired from National Education |  |
| Ms. E. TROCME | Senior Executive Retired Nurse ARUCAH |  | Mr R. MARTINEZ | Retired Health Insurance (ARUCAH member) | X |

The full members (or alternates in the absence of the full member) took part in the vote. **It should be noted that the members involved in the project did not take part in the deliberation.**

**Professeur Jean-Marc CHALOPIN**