

REPORT FROM THE RESEARCH ETHICS COMMITTEE WITH MEDICINES AND HOSPITAL UNIVERSITARI VALL D'HEBRON RESEARCH PROJECTS COMMISSION

Ms. MIREIA NAVARRO SEBASTIÁN, Secretary of the Research Ethics Committee with Medicines of the Hospital Universitari Vall d'Hebron from Barcelona,

CERTIFIES

That the Research Ethics Committee with Medicines of the Hospital Universitari Vall d'Hebron, integrated along with the Hospital Universitari Vall d'hebron Research Projects Commission, held a meeting on 19/03/2021, ordinary session nº 480, and evaluated the following amendment: 2, project CEIm code **PR(AG)480/2018**, titled "*A Pan-European Multi-Centre Observational Study To Determine The Natural History Of Patients With Alpha-1 Antitrypsin Deficiency. / Estudio pan Europeo multicéntrico observacional para determinar la historia natural de los pacientes con déficit de alfa-1 antitripsina.*", whose principal investigator is Dr. Marc Miravittles Fernández of our Hospital.

Documents:

Protocol	V3, March 01, 2021
HIP/CI	versión 5 del 01 marzo 2021

The result of our evaluation was as follows: **Approved**

The Committee in its composition as in the SOP (Standard Operating Procedure) meets GCP (CPMP/ICH/135/95) and Royal Decree 1090/2015, and its current composition is:

Chair person: Gallego Melcón, Soledad. Doctor

Vice President: Segarra Sarries, Joan. Lawyer

Secretary: Navarro Sebastián, Mireia. Chemist

Vocals:

Armadans Gil, Lluís. Doctor

Azpiroz Vidaur, Fernando. Doctor

Balasso, Valentina. Doctor

Cucurull Folgera, Esther. Physician Pharmacologist

De Torres Ramírez, Inés M. Doctor

Estévez Rodríguez, Ana Belén. Layer – data protection specialist
Fernández Liz, Eladio. Primary care Pharmaceutics
Fuentes Camps, Inmaculada. Physician Pharmacologist
Gálvez Hernando, Gloria María. Nurse
Guardia Massó, Jaume. Doctor
Hortal Ibarra, Juan Carlos. Law University Profesor
Iavecchia, María Luján. Physician Pharmacologist
Roca Gas, Oriol. Doctor
Rodríguez Gallego, Alexis. Physician Pharmacologist
Sánchez Raya, Judith. Doctor
Solé Orsola, Marta. Nurse
Suñé Martín, Pilar. Hospital Pharmacologist
Vargas Blasco, Víctor. Doctor
Zuriguél Pérez, Esperanza. Nurse

At the meeting of the Research Ethics Committee with Medicines fulfilled the quorum provisions of law.

In the case of a project to evaluate where a member is a researcher / collaborator, he will be absent from the meeting during the discussion of the project.

Ms. Mireia Navarro
Secretary of Research Ethics Committee with Medicines
Hospital Universitari Vall d'Hebron