

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 10/11/2023, ordinary session nº 599, and evaluated the following amendment: 4, project CEIm code **PR(AG)480/2018**, sponsor Vall d'Hebron Institut de Recerca (VHIR) , titled “*An International Multi-Centre Observational Study To Determine The Natural History Of Patients With Alpha-1 Antitrypsin Deficiency*”, whose principal investigator is Dr. Marc Miravittles Fernández of our Hospital.

Documents:

Protocol	V4, October 16, 2023
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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:

- Presidente:**
- IGNACIO FERREIRA GONZÁLEZ - Médico
- Vicepresidente:**
- JUDITH SANCHEZ RAYA - Médico
- Secretario:**
- MIREIA NAVARRO SEBASTIAN - Química
- Vocales:**
- LLUIS ARMADANS GIL - Médico
- FERNANDO AZPIROZ VIDAUR - Médico
- VALENTINA BALASSO - Médico
- INES M DE TORRES RAMÍREZ - Médico
- ELADIO FERNÁNDEZ LIZ - Farmacéutico Atención Primaria
- INMACULADA FUENTES CAMPS - Médico Farmacólogo
- JAUME GUARDIA MASSÓ - Médico

- JUAN CARLOS HORTAL IBARRA - Profesor de Universidad
- MARIA LUJAN IAVECCHIA - Médico Farmacólogo
- ALEXIS RODRIGUEZ GALLEGO - Médico Farmacólogo
- PILAR SUÑÉ MARTÍN - Farmacéutica Hospital
- ESPERANZA ZURIGUEL PEREZ - Personal de Enfermería
- ANA BELÉN ESTÉVEZ RODRÍGUEZ - Abogada experta en protección de datos
- SANTIAGO ESCRIVÀ DE ROMANÍ MUÑOZ - Médico
- ANTONIO MORENO GALDÓ - Médico
- ESTHER CUCURULL FOLGUERA - Médico Farmacólogo
- SERGI MORALES FERNANDEZ – Abogado
- GLORIA GÁLVEZ HERNANDO - Personal de Enfermería
- NURIA FERNÁNDEZ HIDALGO - Médico

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