

OPINION OF RESEARCH ETHICS COMMITTEE (REC)

Dr. Neus Riba Garcia
Technical Secretary of REC Fundació Sant Joan de Déu

CERTIFIES

That REC of Fundació Sant Joan de Déu at its meeting held on **09/05/2024**, minutes **09/2024**, evaluated the proposal of the promoter regarding the study:

Title: *“International surveillance study for hospital-acquired infection in haemato-oncological patients in PICU (ISHION study)”*

Principal Investigator: Carmina Guitart Pardellans

Promotor: Fundació Privada per a la Recerca i la Docència Sant Joan de Déu – FSJD

Protocol code: ISHION study

REC code: EOM-07-24

Service: UCI

Center: Sant Joan de Déu Hospital

That the REC requested clarifications after the initial assessment.

The permanent commission of the REC Fundació Sant Joan de Déu evaluated the response received to the clarifications.

Documents with versions:

Tipo - Subtipo	Fecha - Versión
Protocol	version 2. 05.09.2024

And that REC considers that:

- THE STUDY MEETS THE DEFINITION OF RESEARCH WITHOUT COMMERCIAL INTEREST as established in paragraph e) of article 2.2 of RD 1090/2015, of December 4, which regulates clinical trials with drugs, the Ethics Committees of the Research with medications and the Spanish Registry of Clinical Studies.
- The project is an OBSERVATIONAL STUDY WITH DRUGS, WITH PROSPECTIVE FOLLOW-UP.
- The project follows the requirements of Royal Decree 957/2020, of November 3, which regulates observational studies with drugs for human use.

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- The necessary requirements for the suitability of the protocol in relation to the objectives of the study are met and the foreseeable risks and discomfort for the subject are justified, taking into account the expected benefits.
- The procedure for obtaining informed consent, including the subject information sheet and the planned subject recruitment plan, are adequate. The Investigators' competency and the feasibility means are appropriate to carry out the study.
- The capacity of the researcher and his collaborators and the facilities and means available are appropriate to carry out the study.
- The scope of the planned economic compensation does not interfere with respect for ethical postulates.

Therefore, this REC issues a **FAVORABLE OPINION** on **23/10/2024**.

And the REC states that:

First, At the meeting held on **09/05/2024**, minutes **09/2024**, it was decided to issue the report corresponding to the reference study.

Second, The REC of the Fundació Sant Joan de Déu, both in its composition and in its SOPs, complies with the BPC regulations (CPMP / ICH / 135/95).

Third, List of members:

President:

- Jesús Pineda Sánchez - Medicine - Pediatrics

Vice president:

- Bernabé Robles Del Olmo - Medicine – Neurology

Technical Secretary:

- Neus Riba Garcia - Clinical Pharmacology

Members:

- Fernando Aguiló Martínez - Medicina Tropical
- Clara Chamorro Pérez - Lawyer
- Ángel del Campo Escota - Representative of patient associations
- Rosa María Dueñas Herrero - Medicine – Psychiatry
- Pau Ferrer Salvans - Clinical Pharmacology
- María Eugènia Rey Abella - Primary care pharmacy
- Ana Martín Ancel - Medicine – Neonatology
- Eduard Puig Vaquero - Lawyer - Data protection officer
- Carlota Romans Ruiz - Medicine – Psychiatry

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- Antoni Noguera Julián - Medicine – Pediatrics
- Edurne Mazarico Gallego - Medicine – Gynecology and Obstetrics
- Esther Via Virgili - Medicine – Psychiatry
- Oriol Martín Solé - Medicine – Surgery and representative of RC
- Maite Gorostegui Obanos - Medicine – Oncology
- Rosa Farré Riba - Hospital pharmacy
- Josep Codorniu Castelló - User Service Unit
- Montserrat Gutierrez Juarez - Nurse

****** In the event that a project for which a member is a researcher / collaborator is evaluated, the member will be absent from the meeting during the project discussion.

For the record and at the request of the applicant,

Signed in Esplugues de Llobregat:

Dr. Neus Riba Garcia
Technical Secretary of REC Fundació Sant Joan de Déu