

Registered protocol n. 22 on 20th January 2022

Coordinator Ethical Committee Approval of the Observational Study: “Practice of Oxygenation and Respiratory Support during Fiberoptic Bronchoscopy: The Oxy-FOB STUDY

Principal Investigator of the Study: Prof. Federico Longhini, Department of Anesthesia and Intensive Care Unit, University Hospital “Mater Domini” in Catanzaro (Italy).

Examined Documents:

1. Letter of intent
2. Protocol in English language
3. Protocol in Italian language
4. Synopsis of the study protocol
5. Information sheet and informed consent
6. Declaration of Conflict of Interest

Ascertained the legal number of the participants and that Components of the Ethical Committee for which there is a conflict of interest of a direct and indirect type, refrain from expressing an opinion.

On the 22nd January 2022, the Ethical Committee “Regione Calabria sezione Area Centro”, headquartered at the A.O.U. Mater Domini in Via Tommaso Campanella, 115 Catanzaro, in the function of Coordinator Ethical Committee, on the basis of the report carried out and verified the documentation sent by the Principal Investigator, expresses a favorable judgement on the Observational Study referred to in the subject.

The Ethical Committee is an independent organization, without hierarchical subordination relationships with respect to the structure in which it operates.

It carries out the evaluation of the ethical aspects of biological and clinical research, in compliance with Legislative Decree no. 211 of 2003, the Declaration of Helsinki in its most updated version, the Oviedo Convention, the standards of good clinical practice referred to in Annex 1 to the Ministerial Decree July 15, 1997, of the guidelines updated by the European Agency for the Evaluation of Medicinal Products regarding the evaluation of the efficacy of clinical trials and the recommendations of the National Bioethics Committee, formulating recommendations, suggestions and opinions (the latter in the presence of a formal request) on fundamental and specific ethical issues.

The organization and its operation are those provided for by the Ministerial Decree of 08 February 2013

This is sent for the fulfillment of the case, according to the respective competences.

Resp. Segreteria Tecnico-Scientifica
Comitato Etico
(Dott. Luigi Mancuso)



Il Presidente
Comitato Etico
(Prof. Pietramaria Ricci)

