

Prot.N. 0018656/P/GEN/ARCS
Date: 25/06/2019

R.A. FRIULI VENEZIA GIULIA

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SINGLE REGIONAL ETHICS COMMITTEE
operational headquarters ONCOLOGICAL REFERENCE CENTER
Scientific hospitalization and treatment institute
Via Franco Gallini, 2 – 33081 AVIANO (PN) tel. 0434 659282

Dear dr. Vetrugno Luigi
Responsible investigator
Integrated University Health Authority of Udine
– SOC Anesthesia and Intensive Care Clinic

Dear Ms Elda Cameranesi
Director of SOC General Affairs ASUI of Udine

SUBJECT: CEUR opinion (meeting dd.04 / 06/2019 – odg 5.18) DISSOLUTION OF RESERVES

competent structure: Friuli Venezia Giulia Single Regional Ethics Committee, via Pozzuolo 330 - 33100 Udine responsible for the procedure: Alessandra Bearz, telephone 0432.1438091, mail committee.etico@arcs.sanita.fvg.it responsible for the investigation: Caterina Comand, telephone 0432.1438092, mail caterina.comand@arcs.sanita.fvg.it contact person for communication: Daniela Gerometta, telephone 0432.1438093, mail daniela.gerometta@arcs.sanita.fvg.it

Study ID	2817
Internal code in the center	NOT APPLICABLE
Type of study	Observational without drug and device
study type	No profit
Study code	LUSHIP
Study title	“Usefulness of lung ultrasound in the preoperative evaluation of patients to undergo emergency orthopedic surgery for fracture of the femur”
Phase	NA
EudraCT	NA
Promoter	Integrated University Health Authority of Udine – ASUI UD
CRO	NA
Center – OU	Integrated University Health Authority of Udine – SOC Anesthesia and Intensive Care Clinic
Coordinating Center	SOC Clinic of Anesthesia and Resuscitation A.S.U.I. Udine
Experimenter	Vetrugno Luigi

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With reference to the study indicated and the previous communication Prot. N. 17261 of 12.06.2019 for the transmission of the "sub-conditional" opinion, **it is believed that the documentation indicated below sent by e-mail on 21.06.2019:**

- Information sheet, consent form and revocation form for the processing of personal data v. 4.0 dated 20.06.2019
- Information sheet, consent form and withdrawal form for participation in the study v. 4.0 dated 20.06.2019
- Letter to the GP v. 4.0 dated 20.06.2019
- Anonymized data sheet

complies with the requirements. It is confirmed that the changes requested by the Committee have been accepted, the reservations are therefore dissolved and the favorable opinion already expressed in the meeting of 04.06.2019 is definitively confirmed:

CEUR-2019-Os-101 Opinion

Please note that this Ethics Committee must be informed of the start and end date of the study, of any suspension or interruption, for any reason.

This letter does not constitute authorization to start the Study, at the Operational Structure at address, and that this authorization will be formalized with a subsequent decree of the Company Management where the study is carried out.

In transmitting a bit, we take the opportunity to extend our best regards.

the President of the Single Regional Ethics Committee Dr. Paolo Rossi

Digitally signed

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The Single Regional Ethics Committee, established pursuant to the Decree of 8 February 2013 and Regional Law no. 33 of 29.12.2015, with DGR 22 January 2016 n. 73, Decree n. 414 / SPS of 03.31.2016, and Decree 694 / SPS of 05.31.2016, operates in compliance with the provisions of the Ministerial Decree of 15 July 1997, of Circular no. 15 of 15 October 2000, by Legislative Decree n. 211 of June 24, 2003, and in compliance with the rules of Good Clinical Practice (GCP-ICP).

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