# **Information on data processing on the FENICE II Study (legal representative)**

Title of the Study: **Fluid Challenge in Intensive Care: A Worldwide Global Inception Cohort Study. The FENICE II trial.**

Sponsor and Coordinating Center: IRCCS Humanitas Clinical Institute

Principal Investigator: Prof. Maurizio Cecconi

Center: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**WHO WILL PROCESS PATIENT’S DATA?**

This Hospital \_\_\_\_\_\_\_\_\_\_\_, with registered office in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (hereinafter the "**Center**”) and the Sponsor and Coordinating Center of the Fenice2 study, **IRCCS Istituto Clinico Humanitas - Humanitas Mirasole SpA**, with registered office in Rozzano (Milan), Via Alessandro Manzoni 56, (hereinafter the " **Sponsor of the study**”)will process the patient’s personal data as autonomous Data Controllers.

**WHICH DATA WILL BE PROCESSED AND WHY?**

To carry out the study, the researchers will process information concerning the patients both of a simple nature (such as identifier, age, height, or weight...), and “belonging to special categories” and especially relating to his/her health status. The Investigator of this Center will collect data relating to the patient’s age, gender, reasons for admission to the ICU (Intensive Care Unit), and a series of clinical data during the hospitalization phase at the ICU. Specifically, the Investigator at this Center will collect only those personal data strictly necessary for the achievement of the objectives of Study F2 and will share it with the Sponsor. Consent is required for the processing of the patient’s personal data.

For the purpose of signing this consent document and other required procedures, in compliance with the relevant European regulatory requirements, simple personal data (identifying, housing and contact information) of individuals who have legal representation of the data subject (lacking “capacity to act”) are also collected and processed in accordance with all the provisions set forth below.

**WHAT SECURITY MEASURES ENSURE CONFIDENTIALITY?**

Specially authorized clinical and research staff will process the patient’s data and identify him/her with a numeric or alphanumeric code that will be assigned to each participant: data will be processed and stored identified by this code in a dedicated database with limited access in the Center. Only the aforementioned personnel involved in the study will be able to link this code to the patient’s name, for any other recipients of the information (included the Sponsor) will only be linkable to the code, protecting his/her identity. All personnel involved in data analysis are anyway obliged to keep such information confidential.

Some statistical tests will be carried out on the patient’s data, together with those collected for the other patients included in the scope of study. All data will be processed using electronic tools with the adoption of adequate security measures and following an appropriate impact assessment regarding the protection of personal data.

**WHO WILL BE ABLE TO ACCESS PATIENT’S DATA?**

Patient’s personal data will be processed by the authorized personnel of this Center and of the Sponsor, that’ll receive those information pseudonymized as above.

The data may be accessed by third parties in a contractual relationship for administrative or institutional purposes who operate, depending on the case, as Data Controllers or Data Processors.

In any case, the list of processors is available at the Sponsor’s headquarters or by writing to privacy@humanitas.it.

The Ethics Committee of this Center, the Health Authorities, and the medical staff responsible for verifying the data/procedures will be able to inspect the data archive without however being able to trace patient’s identity.

**WILL DATA BE TRANSFERRED OUTSIDE THE EUROPEAN UNION?**

Patient’s personal data will be processed in this Country, sent to the Sponsor (with headquarters in Italy) and not be processed and/or transferred outside the European Union.

**HOW LONG WILL PATIENT’S DATA BE KEPT FOR?**

 All data used in this study will be retained by the center and the Sponsor until the end of this study and for the following 2 years. Then they’ll be made anonymous or deleted.

**WHAT ARE PATIENT’S DATA PROTECTION RIGHTS?**

We remind you that you may at any time revoke the patient’s consent to the processing of personal data for the execution of this study without providing any justification, by contacting the Center directly or by writing to \_\_\_\_\_\_\_\_\_\_\_\_. Upon withdrawal of consent, no further data concerning the patient will be processed, without prejudice to the analysis of those already collected to determine, without altering them, the results of the research.

By contacting the Principal Investigator or writing to privacy@humanitas.it you can exercise the rights guaranteed by EU Regulation 2016/679 in articles 15-22 and relevant to this clinical study, and in particular the right to access patient’s personal data, the right to rectification in case of errors or omissions, and, where applicable, the right to data deletion or to the restriction of processing of all data collected for the study. You can also always lodge a complaint with the competent Data Protection Supervising Authority if you notice a violation of current legislation on the matter.

**WHO IS THE DATA PROTECTION OFFICER (DPO)?**

The DPO is the figure who guarantees and supervises compliance with the protection of personal data.

This Center’s DPO can be contacted at the following address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The Sponsor’s DPO can be contacted at the following addresses: Via Manzoni 113 - 20089 Rozzano (Milan), e-mail: dataprotectionofficer@humanitas.it

**EXPRESSION OF CONSENT FOR DATA PROCESSING**

Read and understood the information on data processing:

 **I consent to the processing of the patient’s personal data for the execution of this clinical study.**

 **I do not consent to the processing of the patient’s personal data and will not proceed to participate.**

**Date** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Patient's name, surname, and signature** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_