STUDY FACT SHEET

Title of the Study:
- PRospective multicenter Observational study on Transfusion practice in vv-ECMO patients: the PROTECMO study.
- Prospective multicenter observational study on transfusion practice in vv-ECMO patients: the PROTECMO study. (version update 01-10-2018)

Protocol # IRRB/15/17

Sponsor IRCCS – ISMETT

Experimentation Center: **[insert name of experimentation center]**

Principal Investigator: ……
Total number of pages (the last page is the **informed consent form**): 4

Dear Sir/Madam

1. Introduction

The experimentation center [**insert name of experimentation center**] intends to start the medical-scientific research in the header (hereinafter referred to as "**Study**"), sponsored by IRCCS Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione S.r.l. – ISMETT (hereinafter referred to as "**Sponsor"**). The purpose of the study is to assess, taking into consideration the practice of the various centers around the world, the main factors that lead to performing transfusions in severely critical patients on Extracorporeal Membrane Oxygenation (ECMO) support.
In recent years, several studies have revealed that there are different approaches worldwide concerning transfusions during ECMO support therapy.
At the same time, in accordance with recent scientific evidences, there has been a reduction in the quantity of blood products transfused in critically ill patients. However, not all specialty centers in the field accept a restrictive approach during ECMO treatment due to some of its specific characteristics: risk of bleeding, hypoxia in patients with severe acute respiratory failure, and presence of a large extracorporeal circuit.
The goal of our study is therefore to understand what factors drive the decision of centers providing ECMO to transfuse blood products, and to verify if a variation of the transfusion approach has an effect on successful clinical indicators.
This is a multicenter prospective observational study.
This is an **observational** study that, from the time of your inclusion, will therefore only consider data obtained from your clinical record and resulting from the standard clinical practice implemented at the Center according to clinical decisions and set protocols for patients treated with ECMO. The participation in the Study does not require any type of therapy, procedure, or visit in addition to those provided by standard clinical practice for your condition.
This is a **prospective** study in the sense that all data used for the Study will be collected only from the moment you are included in the Study after signing the consent.
This is a **multicenter** study in the sense that it will be carried out on patients admitted, also at other centers in Italy and abroad, for ECMO support, but will be assessed only by staff of the Sponsor (ISMETT).
To conduct this Study it is necessary to have the collaboration and availability of people who like you are scientifically eligible for the assessment that will be performed.

For these reasons, we invite you to participate in this Study that is illustrated to you by Dr. […….. , Tel. …….] principal investigator at the Center.
Before you decide whether or not to accept, we kindly ask you to carefully read this document and ask for any clarification or information you may require.
Also, before you decide, please feel free to consult your family members and of your family doctor.

2. Purpose of the Study

The purpose of the Study is to assess, taking into consideration the practice of various centers around the world, the main factors that lead to performing transfusions in seriously critical patients on ECMO support.

3. Procedures of the Study

If you agree to participate in the Study you will be asked to sign the Informed Consent Form included at the end of this Fact Sheet, and the Informed Consent to Personal Data Processing, at the end of the according fact sheet.

During the Study your personal and clinical data will be collected and analyzed by the investigator. If you agree to participate in this Study you will not undergo any visit, therapy, or blood sampling in addition to the standard clinical practice.

The Study will last for 1 year from your enrollment.

At ……. an involvement is estimated of approximately [10 patients] suffering your same pathology and who will admitted for ECMO support.
If you agree to participate in the Study you will not be asked to follow any specific prescription.
Your participation in this Study involves no costs or use of time for you.

4. Clinical/instrumental tests foreseen in the Study Protocol

The Study does not include tests in addition to those that the multidisciplinary team of……. will prescribe for you during the standard clinical practice at the time of admission and during subsequent follow-ups.

5. Foreseeable risks of the Study

Your participation in this Study will entail no risks for you as you will undergo no procedure related to the start and development of the Study.

6. Foreseeable benefits of the Study

You shall receive no direct benefit from your participation in this Study. However, your participation is by all means useful to allow to identify with more precision and scientific valence the most frequent factor that leads to perform transfusions of blood products, and to verify if different strategies have different effects for the patients.

9. Participation in the Study

The decision to participate in this Study is entirely up to you.

If you decide to participate, you will be free to withdraw from the Study at any time without the obligation to provide an explanation.
Should you refuse to participate or to withdraw at any time, your decision will not result in any loss of medical care to which you are otherwise entitled for your disease, and the doctors will continue to follow you with due care.

Should we become aware of data or results that may influence your intention to participate in the Study, you will be promptly informed.

10. Insurance

Given the observational nature of the Study and the consequent absence of risks, there is no need for an insurance policy as a guarantee to enrolled patients.

11. Results of the Study

At your request, at the end of the Study you will be notified of the overall general results and, where possible, also of the specific results that concern you.

12. Information on the Study

During the Study, the Principal Investigator will provide any additional information you may require.

The Study Protocol proposed to you was drafted in compliance with the European Union (EU) Good Clinical Practice Directive, in accordance with the Declaration of Helsinki, and was approved by the Ethics Committee.

Thank you for taking the time to read this document.
If you decide to participate in the Study you will receive a copy of this Fact Sheet and a signed copy of the informed consent form.

_____
Signature of the physician providing the information note [clear]

For receipt of the Fact Sheet

[*name and last name of the patient in block letters*]……..

_____
Patient's signature

(FORM #1)
STATEMENT OF CONSENT FOR AN ADULT AND CAPABLE INDIVIDUAL

I, the undersigned……, born in.....on..... (taxpayer's code) declare I received from Dr. ……. detailed explanations on the request of my participation in the Study described above, and that I received a copy of this Fact Sheet.
I was able to discuss the content of the Fact Sheet that was given to me, I was able to ask all the questions I deemed necessary and these were answered to my satisfaction.
It was also suggested to me that I should discuss my participation in the Study with other people whom I trust, and particularly with my family doctor.
I therefore freely agree to participate in the Study, having perfectly understood all the above information.
I am aware that my participation in the Study is voluntary, that I have the right to withdraw at any time, and that this will not result in any loss of medical care which I am otherwise entitled and/or may need.
I have been **informed** of my right to have free access to the medical documentation relating to the Study.

Date ……..
[*name and last name of the patient in capital letters*]……..

signature [legible] ……...……..

Please complete this section if the person, although capable to legally express his/her consent, is unable to physically sign. The witness must be an independent person with respect to the Study and a third party with respect to the person obtaining the consent.
I declare that the patient is unable to physically sign. I have personally witnessed that the patient received all the information related to the Study and referred to in the Fact Sheet included herein, and that the patient, having understood this information, verbally expressed his/her consent to participation in the Study.

[name and last name in block letters of the impartial witness and ID card number] ……..

Signature…….. date…….

[*name and last name in capital letters of the PI/member of experimental team*] ……

_____
Signature of the investigator ……...…… Date ……..

(FORM #3)
STATEMENT OF CONSENT FOR A PERSON INTERDICTED OR ASSIGNED TO A TRUSTEE

(please use this form in the case of a person interdicted or assigned to a trustee. This Statement must be signed and dated personally by the Guardian or Trustee after signing the related self-statement. These persons must have previously received the Fact Sheet and its content duly illustrated).

I, the undersigned.....
(name and last name of the Guardian/Trustee*) in the capacity of* ..... (specify the capacity of the person*)* of .....(specify the person in whose interest the consent is expressed*)* declare that I have received from Dr. ……. (name and last name of the PI*)* detailed explanations regarding the request of participation of ..... (insert name and last name of the patient*)* to the Study described above. I have received a copy of the above mentioned Fact Sheet.
I was able to discuss the contents of the above-mentioned Fact Sheet and to ask all the necessary questions, and I received satisfying answers to my questions.
Also, I was told I could discuss my participation to the Study of (insert name and last name of the incapable person) with other people who I trusted, and particularly with the doctor treating the patient.
I therefore accept the free participation of (*insert name and last name of the incapable person*) to the Study, having perfectly understood all the above information.
I am aware that the above mentioned participation in the Study is voluntary and that I have the right at any time to revoke this consent, and that this will not result in any loss of medical care that (*insert name and last name of the incapable person*) requires or may require.
I am aware of the will expressed by (*insert name and last name of the incapable person*) referred to in the the statement below.
I have been **informed** of my right to have free access to the medical documentation relating to the Study.
[*name and last name in capital letters of guardian/trustee*]

_____ _____
Signature of the guardian/ trustee Date

[name and last name in block letters of the PI/member of experimental team]

_____ _____
Signature of the PI Date

STATEMENT OF THE INCAPABLE PERSON TO PARTICIPATE IN THE STUDY
(modify according to the ability to understand of the incapable person, provided he/she is able to express an opinion and assess the information he/she has received).

Please note: *the principal investigator must take into consideration the explicit will of the incapable person to refuse to participate in the experimentation or to*

*withdraw at any time, if the latter is able to express an opinion and assess the information he/she has received [***art. 5, Legislative Decree 211/03***]*

1. Your name is [identify the incapable person by entering his/her name*].*

2. We are asking you to participate in a study because we are trying to learn something about [*explain the subject of the experimentation using words suitable to the person's ability to understand*]

3. If you agree to participate in this study [*explain what will happen from the point of view of the incapable person, using words suitable to his/her ability to understand*]

4. [Describe potential risks that may arise for the underage person [Translator's Note: "minore" in Italian version] from his/her participation in the study*]*

5. [*Describe the direct benefit that the incapable person may have his/her participation in the study*]

6. You may ask anything you want on this Study. If later on you think of other things you haven't asked me now, you can call me at this number [*add phone number*] or you can ask me other questions next time we meet. [*If appropriate: you can call me at any time to ask me anything on your disease or your treatment*.]

7. Your doctors will continue to treat you notwithstanding your participation in the study. We will give you and your legal representative a signed copy of this form.

I want to participate □ / not participate □/ I express no will □

[name and last name in block letters of the incapable person] …….

_____ _____

Signature of the incapable person Date

[name and last name in block letters of the PI/member of experimental team]

_____ _____

Signature of the PI Date