# PATIENT INFORMATION SHEET

# &

# INFORMED CONSENT TO BE SIGNED

## Title of the Study

Evaluation of the ability of the MEESSI-AHF scale to improve decision making and prognosis in patients diagnosed with acute heart failure in the emergency department

(Version 2)

## Date of submission to Ethical Committee

April 4th, 2018

## Date of approval by Ethical Committee

April 4th, 2018

(Internal reference number: HCB/2018/0233)

**STUDY TITLE:** Evaluation of the ability of the MEESSI-AHF scale to improve decision making and prognosis in patients diagnosed with acute heart failure in the emergency department- Study 3 (reference number: HCB/2018/0233)

**PROMOTER:** Òscar Miró, Hospital Clínic, Barcelona

**INTRODUCTION**

We are writing to inform you about a research study in which you are invited to participate. The study has been approved by a Research Ethics Committee, according to the current legislation, Biomedical Research Law 14/2007.

Our intention is only that you receive correct and sufficient information so that you can evaluate and judge whether or not you want to participate in this study. To this end, please read this information sheet carefully and we will clarify any doubts that may arise after the explanation. In addition, you can consult with the people you consider appropriate.

**VOLUNTARY PARTICIPATION**

You should know that your participation in this study is voluntary and that you can decide not to participate or to change your decision and withdraw your consent at any time, without altering the relationship with your doctor or any detriment to your treatment.

**GENERAL DESCRIPTION OF THE STUDY**

Until now, the decision to admit or discharge patients diagnosed with acute heart failure in the emergency department, as in your case, has been based on the experience of the attending physician. No tool is applied to estimate the risk of complications during the month following the diagnosis of heart failure in the emergency department. Therefore, this decision is currently made in a relatively subjective manner with no empirical data (from studies) to support it, and with certain heterogeneity depending on the physician, the emergency department or the hospital attending the patient.

During the last few years our group has developed a scale to estimate this risk (during the 30 days following diagnosis), called the MEESSI-AHF scale. When applied, the scale performs a mathematical calculation that allows the patient to be classified as having a low, medium, high or very high risk of complications. To do this, the mathematical program that performs the calculation must be provided with a series of parameters that are obtained routinely in the emergency care process, without this involving any medical, analytical or other type of examination additional to the routine care process. Since we do not know whether the application of this MEESSI-AHF scale entails any benefit or risk in routine clinical practice, we decided to carry out this study.

In the present study, IF YOU DECIDE TO PARTICIPATE, the attending physician will access a randomly ordered list, not previously known to him, and this list will assign you to one of the following two possibilities: stratification of your risk using the MEESSI-AHF scale prior to the admission or discharge decision (Intervention Group) or decision making based on usual clinical practice, without using the MEESSI-AHF scale (Control Group). The chances of being assigned to one or the other group will be 50% for each of them. The attending physician will know to which group you have been assigned.

If you are assigned to the Intervention Group, your risk will be calculated by entering parameters in the calculator. This will allow you to be stratified into one of the four risk categories mentioned above. If your category is low risk, the scale suggests to the attending physician that home discharge may be safe and that he/she may proceed with discharge if he/she deems it appropriate. If your risk category is medium, high or very high, the scale suggests to the physician that hospital admission would be most appropriate. However, your risk category, whatever it may be, does not oblige any specific decision and is only one more element that the attending physician will take into account when making his decision, which will be, as always, shared with the patient and his family and which, in the end, will be the one they decide in what they understand to be their best clinical benefit. Knowing your risk category takes no more than five minutes for the attending physician and is of no inconvenience to you. And since the ultimate decision of admission or discharge will be made freely by your physician, there is no risk to you in participating in this study.

If you are assigned to the Control Group, the attending physician will make the decision to admit or discharge you as has always been done, following the usual medical practice: based on his or her personal experience and on the comprehensive assessment of your clinical condition and the results of the complementary examinations that have been performed.

You should be aware that if you decide to participate in the study, whichever group you are assigned to, the physician or the medical research team will collect clinical data related to your disease for subsequent analysis. However, your participation in the study, whatever your group of assignment, does not change any treatment to be administered (it will always be those that your attending physician decides), will not involve any additional clinical examination (you will undergo the same analyses, X-rays, electrocardiograms or other examinations that would be done if you did not participate in the study) and does not entail any additional visit to the emergency room, hospital or health center (the usual controls that are currently applied will be followed according to each usual case).

As we are interested in knowing how your evolution has been, independently of the group to which you are assigned, you will be contacted by telephone after 30 days and then on a second occasion, one year after your emergency care. In addition, your inpatient and outpatient medical records will be consulted to complement this follow-up. By agreeing to participate in this study, you authorize us to make these contacts and consultations.

Alternatively, IF YOU DECIDE NOT TO PARTICIPATE IN THE STUDY, your physician will not apply the MEESSI-AHF scale, your risk of complications will not be calculated and your risk category will not be known. Therefore, the attending physician will make the

decision to admit or discharge you as he/she has always done: based on his/her personal experience and on the comprehensive assessment of your clinical condition and the results of the complementary examinations that have been performed.

**BENEFITS AND RISKS DERIVED FROM YOUR PARTICIPATION IN THE STUDY**

The main expected benefit of this study is to determine whether risk stratification of patients with acute heart failure prior to making a decision in the emergency department (ie, discharge to home or hospital admission) is beneficial for patients and results in a lower number of adverse events: revisits to the emergency department, hospitalizations or rehospitalizations, or death. This is therefore a potential future benefit for society in general and for patients with the same disease as you in particular. In your particular case, participation in the study may not be of any benefit to you. No risk is foreseen either, since the final decision on admission or discharge will not be made by the group to which you have been assigned (nor by your risk category if you are in the Intervention Group), but will be made by your attending physician in agreement with you and your family members.

**OTHER RELEVANT INFORMATION**

Any new information concerning the study that may affect your willingness to participate in the study that is discovered during your participation will be communicated to you by your physician as soon as possible. If you decide to withdraw consent to participate in this study, no new data will be added to the database. You should also be aware that you may be excluded from the study if the study sponsor or investigators deem it appropriate, either for safety reasons or because they feel that you are not complying with the established procedures. In either case, you will receive an adequate explanation of the reason for your withdrawal from the study.

By signing the attached consent form, you agree to comply with the study procedures outlined to you. During the study and at the end of your participation, you will receive the best available treatment that your physician considers most appropriate for your disease. However, as this study does not analyze any drug, neither the investigator nor the sponsor make any commitment to provide any medication.

# Participant Consent Form

**Study title: "Evaluation of the ability of the MEESSI-AHF scale to improve decision making and prognosis in patients diagnosed with acute heart failure in the ED - Study 3"**

Reference number: HCB/2018/0233

I, _____(participant's name and surname)

- I have read the information sheet given to me about the study.
- I have been able to ask questions about the study.
- I have received enough information about the study.
- I have spoken with: _____(name of investigator)
- I understand that my participation is voluntary.
- I understand that I can withdraw from the study:
- Whenever I want.
- Without having to explain myself.
- Without any repercussions on my medical care.

- In accordance with the provisions of Law 15/1999, of December 13, 1999 on the Protection of Personal Data, I declare that I have been informed of the existence of a file or processing of personal data, the purpose of the collection of such data and the recipients of the information.

- I freely give my consent to participate in the present study:

Singed by the participant

Date: ____/____/____

Signed by the researcher

Date: ____/____/____

I wish to be informed of information derived from the research that may be relevant to my health:

☐ Yes ☐ No

Signed by the participant

Date: ____/____/____

Signed by the researcher

Date: ____/____/____