PATIENT INFORMATION SHEET

1. Study Information

Study Title:

Management Of Severe sepsis in Asia's Intensive Care unitS – the MOSAICS study

Intensive Care Unit (ICU) Investigator & Contact Details:

_____

2. Purpose of the Research Study

You are invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this research study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You are invited because you have severe sepsis, i.e. a severe infection which is associated with organ failure.

This study is carried out to find out how severe sepsis is managed in the ICUs of Asia. This study will recruit about 2000 patients from ICUs in many countries in Asia over a period of 1 month.

3. What procedures will be followed in this study

If you take part in this study, medical data will be collected during your hospitalization stay. The data will focus on the type of monitoring and treatment (including medications and support on any artificial breathing machine) provided for you during and/or just before your ICU stay. The nature and severity of your infection will also be recorded.

This is purely an observational study, it does not affect your treatment.

You are not required to take any study medication; there is no intervention.

No additional blood test is required.

Your participation in the study will last the entire hospitalization stay, or for 28 days after the diagnosis of severe sepsis, whichever is later.

You will not incur any additional cost.

4. Your Responsibilities in This Study

If you agree to participate in this study, you should allow the necessary medical data to be recorded.

5. What Is Not Standard Care or Experimental in This Study

Nothing. This study does not change the care provided for you by your hospital.

6. Possible Risks and Side Effects

As this is a purely observation study involving prospective data collection, there is no risk to you. The treatment is left entirely to the discretion of the attending physician, in accordance with existing standard practices and protocols.

7. Possible Benefits from Participating in the Study

Strictly speaking, participation in this study may only benefit future patients as this study hopes to provide information on current management practices for severe sepsis in Asia and thereby highlight possible areas for improvement. However, although not primarily an intended effect of the study, it is possible that participation in the study may result in optimization of your care by your attending physician.

8. Alternatives to Participation

If you choose not to take part in this study, you will still receive standard care for your condition. I.e. there are no adverse consequences if you choose not to take part.

9. Costs & Payments if Participating in the Study

You will not incur any cost if you take part in this study.

There is no reimbursement as no additional therapy or intervention is given.

10. Voluntary Participation

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should tell the ICU Investigator.

Your doctor, the ICU Investigator and/or the study committee may stop your participation in the study at any time if they decide that it is in your best interests. If you have other medical problems or side effects, the doctor and/or nurse will decide if you may continue in the research study.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you *(or your legally acceptable representative, if*

relevant) will be informed in a timely manner by the ICU Investigator or his/her representative.

11. Legal rights

Please note that no injury is expected from this study *per se* since the study is purely observational. Nevertheless, by signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

12. Confidentiality of Study and Medical Records

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. In addition, your records will be anonymised.

However, your hospital and the ethics committee will be granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you (*or your legally acceptable representative or next of kin, if relevant*) are authorizing such access to your study and medical records.

In the event of any publication regarding this study, your identity will remain confidential.

13. Who To Contact if You Have Questions

If you have questions about this research study, you may contact the ICU Investigator:

_____

The study has been reviewed by the hospital's ethics committee for ethics approval.

If you want an independent opinion of your rights as a research subject you may contact the ethics committee at:

_____

If you have any complaints about this research study, you may contact the ICU investigator or the ethics committee.

CONSENT FORM

Study Title:

Management Of Severe sepsis in Asia's Intensive Care unitS – the MOSAICS study

Intensive Care Unit (ICU) Investigator & Contact Details:

_____

I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction.

_____	_____	_____
Name of Patient	Signature	Date

Translator Information
The study has been explained to the participant in _____ (language)

by _____ (name of translator).

Witness Statement
I, the undersigned, certify to the best of my knowledge that the participant signing this informed consent form had the study fully explained in a language understood by him / her and clearly understands the nature, risks and benefits of his / her participation in the study.

_____	_____	_____
Name of Witness	Signature	Date

Investigator Statement
I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of her participation in the study.

_____	_____	_____
Name of Investigator / Person administering consent	Signature	Date

ASSENT FORM

for patients who are unfit or unable to provide consent

Study Title:

Management Of Severe sepsis in Asia's Intensive Care unitS – the MOSAICS study

Intensive Care Unit (ICU) Investigator & Contact Details:

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I voluntarily provide consent on behalf of the below-named patient to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction.

_____	_____	
Name of Patient	My relationship to the patient	
_____	_____	_____
Name of legally acceptable representative or next of kin	Signature	Date

Translator Information

The study has been explained to the participant in _____ (language)

by _____ (name of translator).

Witness Statement

I, the undersigned, certify to the best of my knowledge that the participant signing this informed consent form had the study fully explained in a language understood by him / her and clearly understands the nature, risks and benefits of his / her participation in the study.

_____	_____	_____
Name of Witness	Signature	Date

Investigator Statement

I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of her participation in the study.

_____	_____	_____
Name of Investigator / Person administering consent	Signature	Date