

# IRB & DSRB Application Form

## Annex E – Waiver of Informed Consent

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Doc Name :  
IRB & DSRB Application Form Annex E – Waiver of Informed  
Consent

Doc Number : 205-006

Doc Version : 2.0

Date : 19 January 2007

### PROTOCOL TITLE:

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

The IRB / DSRB may waive the requirement to obtain informed consent if the IRB / DSRB find that the study meets specific criteria. Please elaborate & justify if your study meets the following criteria:

1) *Does the study pose no more than minimal risk to the Participants?*

Yes, this study involves no risk. This is merely an observational quality audit on management practices in severe sepsis. The bulk of the data collected will be from the patients' medical records which document what has been done for the patient. The intention of the study is merely to capture information on "real world" practice and as a result, no additional investigations or change in management is required.

2) *Does the waiver of informed consent adversely affect the rights and welfare of the Participants?*

No, it does not affect the rights and welfare of the patients. The review of patients' medical records is for focused prespecified medical information, and the information is not sensitive in nature. There is an extremely low probability of harm to the patients' status, employment, or insurability. Keeping patients anonymous will prevent a breach of confidentiality.

3) *Can the study be practically conducted without the waiver of informed consent?*

No, it cannot be practically conducted without the waiver of informed consent. This is a multinational study involving more than 10 countries in Asia - and a waiver of informed consent is being requested for all countries. In Singapore alone, 10 ICUs are participating. To be as representative as possible, all patients with severe sepsis must be included in this study. Unfortunately, most of these patients are either encephalopathic or intubated and sedated and obtaining consent from them will be impossible.

Obtaining consent from their surrogates will also be difficult - the study aims to capture information within 6 hours of the recognition of severe sepsis and surrogates are often not available at such short notice. To ask these surrogates for consent later on may also only serve to increase their emotional distress and potentially intrude into their privacy when their loved ones are critically ill. Such actions may be deemed inappropriate when the primary objective of the study is more focused on how our doctors practise, rather than on the patients per se.

Without a waiver of informed consent, it is predicted that many patients will not be recruited in time, and this will drastically affect the validity of the study.

4) *Whenever appropriate, will the Participants be provided with additional pertinent information after participation?*

No.

5) *Do you have any additional comments supporting the waiver of informed consent?*

Waiver of informed consent is fairly routine internationally for observational studies in intensive care, and especially for quality audits on management practices. These apply even to landmark multicentred and multinational studies published in high impact journals.

To illustrate, our proposed study is actually based on a study published in JAMA: Ferrer R, Artigas A, Levy MM, Blanco J, González-Díaz G, Garnacho-Montero J, Ibanez J, Palencia E, Quintana M, de la Torre-Prados MV; Edusepsis Study Group. Improvement in process of care and outcome after a multicenter severe sepsis educational program in Spain. JAMA. 2008 May 21;299(19):2294-303.

In this study, the compliance of multiple ICUs in Spain on the Surviving Sepsis Campaign guidelines was reported. This study did not mandate additional investigations or alter treatment for the individual patient. As reported in the manuscript, "the need for informed consent was waived in view of the observational and anonymous nature of the study".

There are many other examples of similar multicentred studies in high impact journals in which informed consent was waived. These include:

The study of how mechanical ventilation practices: Esteban A, Anzueto A, Frutos F, Alía I, Brochard L, Stewart TE, Benito S, Epstein SK, Apezteguía C, Nightingale P, Arroliga AC, Tobin MJ; Mechanical Ventilation International Study Group. Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study. JAMA. 2002 Jan 16;287(3):345-55.

As well as: Esteban A, Ferguson ND, Meade MO, Frutos-Vivar F, Apezteguia C, Brochard L, Raymonds K, Nin N, Hurtado J, Tomicic V, González M, Elizalde J, Nightingale P, Abroug F, Pelosi P, Arabi Y, Moreno R, Jibaja M, D'Empaire G, Sandi F, Matamis D, Montañez AM, Anzueto A; VENTILA Group. Evolution of mechanical ventilation in response to clinical research. Am J Respir Crit Care Med. 2008 Jan 15;177(2):170-7. Epub 2007 Oct 25.

The study of end-of-life practices in Europe: Sprung CL, Cohen SL, Sjokvist P, Baras M, Bulow HH, Hovilehto S, Ledoux D, Lippert A, Maia P, Phelan D, Schobersberger W, Wennberg E, Woodcock T; Ethicus Study Group. End-of-life practices in European intensive care units: the Ethicus Study. JAMA. 2003 Aug 13;290(6):790-7.

The study of adherence to other clinical practice guidelines: Quenot JP, Mentec H, Feihl F, Annane D, Melot C, Vignon P, Brun-Buisson C; TECLA Study Group. Bedside adherence to clinical practice guidelines in the intensive care unit: the TECLA study. Intensive Care Med. 2008 Aug;34(8):1393-400. Epub 2008 Mar 26.

And the study of how hospital volume affects outcomes: Kahn JM, Goss CH, Heagerty PJ, Kramer AA, O'Brien CR, Rubenfeld GD. Hospital volume and the outcomes of mechanical ventilation. N Engl J Med. 2006 Jul 6;355(1):41-50.