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**To the Presidents of European National  
Societies of Intensive Care Medicine  
To the President of the European Respiratory  
Society  
To the President of the European  
Resuscitation Council**

## **AN OPEN LETTER FROM THE EUROPEAN SOCIETY OF INTENSIVE CARE MEDICINE TO ALL NATIONAL AND INTERNATIONAL SOCIETIES INVOLVED IN EMERGENCY AND CRITICAL CARE**

We are writing an open letter to the leadership of national and international societies involved in emergency and critical care to propose a co-ordinated approach to the serious challenges presented to clinical research in incompetent patients by the European Directive 2001/20/CE on clinical research which will be implemented in May 2003 and take effect from 2004.

The Directive makes it mandatory to obtain informed consent either directly from the patient, or indirectly from a 'legal representative'. There are two consequences arising from this requirement. First, in many countries there is no formal legal basis for surrogate or proxy decision making, and ethics committees have hitherto permitted studies to proceed on the basis of informed assent from close relatives. Second, the time constraints imposed by emergency situations (for example in trauma or resuscitation) would make it impossible to obtain consent for research contemporaneously, deferred consent usually being obtained subsequently if the patient survives, or a waiver of informed consent being permitted in certain circumstances.

The effect of the Directive in those countries which do not have formal mechanisms for recognising surrogate consent will be to prevent any further clinical research in incompetent patients in such diverse circumstances as accident and emergency medicine, trauma, and intensive care. It will also seriously hamper research in disciplines such as psychiatry, geriatrics, neurology, and many others. The Directive will make it impossible for us to continue to evaluate and to improve the quality of care we offer to our patients.

We are therefore asking those of you who have not already done so to take the following actions:

- 1) Contact your national organisations with responsibility for research or research ethics, to clarify the potential impact of the Directive on research in emergency and intensive care medicine, and to propose co-ordinated action at a national level. Feel free to copy this letter and attachment to them.
- 2) Those countries which do not yet have a legal basis for surrogate decision-making will need to consider as a matter of urgency how they can preserve clinical research while also satisfying the Directive's laudable aim of protecting patients' rights. This could be achieved by:
  - a) giving legal validity to the views of close relatives in determining the patient's wishes,
  - b) and by developing rigorous methods for approving research in circumstances where neither consent nor assent could be obtained.
- 3) Then contact your Minister of health and / or all bodies involved in the implementation of the directive and communicate these serious concerns.

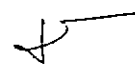
Patients' interests will not be best served by making it illegal to perform clinical research to evaluate and improve the quality of emergency care offered to them.



Graham Ramsay  
*President*



Julian Bion  
*President-elect*



François Lemaire  
*Chair, Consent Task Force*