

**F. Lemaire**  
**L. Blanch**  
**S. L. Cohen**  
**C. Sprung**  
**Working Group on Ethics<sup>1</sup>**

# Informed consent for research purposes in intensive care patients in Europe – part II

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F. Lemaire  
Service de Réanimation Médicale,  
Hôpital Henri Mondor,  
51, avenue du Marechal de Lattre de  
Tassigny,  
F-94010 Créteil, France  
FAX: +33(1) 42 07 99 43

L. Blanch  
Intensive Care Department,  
Hospital de Sabadell, Parc Taulí s/n,  
E-08208 Sabadell, Spain  
FAX: +34 (3) 723 38 63

S. L. Cohen  
UCL Medical School,  
The Rayne Institute,  
5 University Street,  
London WC1E 6JJ, UK  
FAX: +44 (171) 209 62 11

C. Sprung  
Department of Anesthesiology  
and Critical Care  
Medicine, Hadassah University Hospital,  
P. O. Box 12000, Jerusalem, Israel 91120  
FAX: +972 (24) 303 49

<sup>1</sup> Members of the Working Group on Ethics: R. Abizanda (Spain), A. Armaganidis (Greece), F. Blin (France), G. Conti (Italy), W. Dick (Germany), L. Dragsted (Denmark), J. Eklund (Sweden), R. J. Kahn<sup>†</sup> (Belgium), J. R. Le Gall (France), D. Matamis (Greece), N. Mutz (Austria), A. Net (Spain), A. Paes Cardoso (Portugal), S. Ruyter (Norway), H. P. Schuster (Germany) P. M. Suter (Switzerland), J. Takala (Finland), L. G. Thijs (The Netherlands), J. L. Vincent (Belgium), T. Woodcock (UK)

## **Present status of informed consent for research purposes in intensive care patients in Europe**

### **QUESTIONNAIRE**

*Considering all types of clinical research: pharmacological research with or without expected benefit to the patient, epidemiology, . . .*

*1) If you ask for informed consent, could you provide the basis (in English) for obtaining consent. The basis could be: legal, by hospital regulations, by good clinical practice, . . .*

*2) Who decides in your country/ICU that a critically ill patient is competent to give a valid informed consent?*

*3) If it is possible to delegate consent to a surrogate, how the surrogate nominated?: by law, by the family, by the patient at admission? . . .*

*4) Is it possible to do research without informed consent (patient or surrogate) according to an "emergency clause"?*

#### **Austria**

1. The basis for informed consent is given by law and by hospital regulations.

2. The physician decides about the competency of a patient to give a valid informed consent.

3. It is possible to delegate consent to a surrogate. This surrogate is nominated by law, the "family" or patient at admission and by the district attorney in charge in special cases.

4. It is not possible to research without informed consent of patients.

#### **Belgium**

1. The basis for informed consent is given by: 1) European recommendation (R 90-3) concerning research on human; 2) Declaration of Helsinki; 3) Deontological rules; 4) Ethical Committees and 5) Good clinical practice.

2. The physician who performs the investigation has the responsibility to give a judgement on the competency

of the patient. This competent state is needed to be informed and to be able to give a valid informed consent. If the physician has some doubt, he has to ask the opinion of the complete caring team and to inform the family.

3. A legal surrogate exists for children. In the other cases, no official surrogate exists. The close family (or friends) has to be informed and has the right to object (it is a kind of authorization and no more a true consent).

4. It is possible to waive the informed consent for investigations which may have a direct benefit to the patient. A deferred consent has been proposed for studies involving emergency situations.

#### Denmark

1. The basis for informed consent is laid down in the law on patients rights and physicians obligations, dated 20–10–92. Informed consent should be obtained prior to the entrance in a study, that participation in voluntary and that the patient at any time can withdraw from the study and the patient has the right to receive the results of the trial, when the study is finished.

2. The Director of the unit decides whether a patient is competent or not, most often after conference with members of the medical and nursing staff. If the patient is under sedation or analgesics he is not mentally competent. There are no rules laid down by law, only good clinical practice is used.

3. There is no official surrogate and the closest next-of-kin is asked for written informed consent. The next-of-kin can demand that the patient is withdrawn from the study.

4. There is no emergency clause, and research cannot be performed at all without informed consent. A protocol cannot pass the Ethical Committee without informed consent.

#### France

1. The basis for informed consent are regulated by law. A first attempt was the publication by the Ministry of Health in 1987 of a leaflet on “Good Clinical Practices”. On December 20, 1988, Law No. 88-1138 was promulgated. The *Loi Huriet* fixed the rules of informed consent.

This law applies that to “all research works, as soon as organized and carried out on a human being for the development of biological or medical knowledge”. Excluded are research: 1) using already available data, samples obtained without affecting body integrity, or as part and parcel of a necessary therapeutic act; 2) if carried out on corpses, including duly established brain deaths, and having been given death certificate”.

2. No official guidelines have been published about who decides that a critically ill patient is competent to give a valid informed consent. Except in emergency situations, where no one, but the physician in charge of the patient, has the power to decide.

3. Surrogates have no legal status in France at the present time. The *Loi Huriet* states that when biomedical research is effected on a person under age or of age but under guardianship, the consent must be given by the guardians for research with direct therapeutic purpose and, in other cases, by the guardians authorized by the family council or the guardianship judge. A limit of the law is the lack of a clear definition of the next-of-kin. Designation of a proxy or a surrogate by the patient on admission to a hospital might be an improvement.

4. In case of biomedical research in emergency situations, excluding previous consent from the patient himself, a consent may only be requested from the members of his family. The patient will be informed as soon as possible. No biomedical research may be performed on a brain dead person, without his prior consent, or from the testimony of his family.

#### Finland

1. The law (3 July 1985, National Board of Health, Circular 1987) regulates all clinical research. All studies have to be evaluated and approved by the Ethics Committee of the hospitals, and an informed consent is mandatory. In some special circumstances, the need for an informed consent can be waived by the Ethics Committee; these are studies (usually audits), where no interventions for research purpose or changes in routine therapy are involved.

2. Competence for the consent is evaluated by a doctor not involved with the study. As a general rule, patients requiring intensive care are not considered competent, unless consent can be obtained prior to a planned admission to the ICU, e. g. before open heart surgery.

3. A surrogate consent is possible; a surrogate cannot make a legally binding decision, unless he/she is the legal guardian of the patient. Since the majority of surrogate consent involves persons who are not legal guardians of the patient, the format for consent is as follows: the surrogate (the closest family member, unless defined otherwise by the patient) gets the same information about the study as a competent patient would get, and she/he confirms the statement of having received and understood the information regarding the study, and that according to her/his best judgement and personal knowledge of the patient, the patient would not object to participating in the study.

4. An emergency clause might be possible but in practice is not used.

#### Germany

1. The basis for informed consent is good clinical practice, the declaration of Helsinki, and an Ethics Committee.

2. The decision is made separately in each individual case. The patient needs to understand what we are talking about and informed consent is only valid if the patient has confirmed that he has understood everything explained to him. In case of unconsciousness or reduced consciousness, a surrogate or delegate has to be nominated. A physician has to obtain informed consent, usually the ICU resident or the director.

3. A surrogate or delegate giving the consent has to be nominated by a judge in a court of law.

4. It is not possible to do research without obtaining informed consent except perhaps in a therapeutic trial.

#### Greece

With the exception of clinical trials of new drugs or new applications of already known drugs, there are no regulations regarding medical research. In some hospital there is a scientific committee regulating only ethical problems. The law 2071, of July 15, 1992 proposed the creation of both a national ethics committee and local ethics committee in each hospital. The task of these committees will be the regulation of the clinical research (article 61, 62).

1. The basis for informed consent is good clinical practice.

2. If the patient is conscious, informed consent is valid. In general, however, the members of the immediate family are informed.

3. The surrogate is nominated by law, and the usual order is spouse and children, unless upon admission, the patient nominates another person.

4. The next-of-kins are contacted by phone within a very short time. In special cases research could be done without informed consent this is obtained when the next-of-kin arrive at the hospital.

#### Italy

1. The basis for informed consent is local institutional regulations or good clinical practice. Recently, Italy accepted to act in conformity with 91/507/EEC of 19 July 1991.

2. A patient is considered competent if he/she has normal mental status. The mental status is normally evaluated by the physicians in charge.

3. There is no official surrogate by law and the closest next-of-kin is asked for written informed consent in case of decision making incapacity of the patient [1) wife or husband, 2) children over 18 years old, 3) parents for minors].

4. No law restricts research without informed consent according to an "emergency clause". However, it is an accepted practice not to perform research without a written informed consent, at least from the closest next-of-kin.

#### Israel

1. The basis for informed consent is good clinical practice and the "Public Health Regulations (Medical Trial in Humans), 1980". Medical experiments in humans are permitted only after permission is obtained from the Director of the Ministry of Health. Permission is given by the Director if 1) the Hospital's Helsinki Committee approves the experiment, 2) the experiment is in accordance with the Declaration of Helsinki, and 3) for new drugs or technologies, an opinion from the Director of Food and Drugs in the Ministry of Health is obtained.

2. A physician usually decides if a patient is incompetent. If there is a question, a psychiatrist is called.

3. Legally, consent is obtained from the patient or authorized legal representative. In practice, family members sign when the patient lacks decision making capacity.

4. Informed consent is required. In rare instances, deferred consent may be allowed. Epidemiological research not requiring patient identification or extra procedures for the purposes of the research may be permitted by a Helsinki Committee who may waive the requirement for informed consent.

#### Norway

1. There are no explicit laws regulating clinical research in Norway. However, physicians must have research protocols evaluated by an independent regional research ethics committee. In September 1987, The National Committee for Medical Research Ethics published guidelines for obtaining informed consent in biomedical research. The basis for obtaining informed consent follows the Declaration of Helsinki.

To the extent questions of research encompasses biotechnology in medicine these are regulated by The Act relating to the Application of Biotechnology in Medicine (June 14, 1994). According to chapter 6, section 6–

4, written consent must be obtained in connection with genetic testing.

2. The attending physician decides whether a critically ill patient is competent to give consent to participate in research. The decision is based on clinical judgement regarding comprehension, ability to assess participation in research (motives, risks, etc.)

3. According to general law proxy consent can only be given by parents for their children and by legally appointed proxy for legally incompetent persons. In Norway close relatives cannot give proxy consent for incompetent adults. Regarding children it is generally accepted that children above the age of reason should be heard (at least from the age of twelve), and that children above the age of 16 should give consent themselves to research in addition to the consent of parents.

4. Clinical research must be evaluated by regional research ethics committees. Some committees will allow for exceptions in some cases of clinical research without obtaining consent, if certain conditions are met, e.g. the research is done on critically ill patients and is thought to have direct benefit to the patient, there are no available treatment that has better chances of saving the life of the patients, it is impossible to obtain consent (e.g. the patient is unconscious), and the risk is negligible.

#### Portugal

1. The basis for informed consent is given by law and by Hospital Regulations (Ethics Committee).

2. The physician decides about the competency of the patient to give a valid informed consent.

3. It is possible to delegate consent to a surrogate who is nominated by the law (children and incompetent patients), by the patient, or by the family.

4. The patient's informed consent is absolutely necessary for any research.

#### Spain

1. Informed consent is theoretically mandatory in Spain by law (General health Act, 1986 and Law No.25/1990 of 20 December 1990 on medicaments), but no practical implementation, up to now, of this law, with exception of controlled clinical trials with drugs, is systematically followed by Spanish hospitals. Nevertheless, the National Health Service is now on the effort of preparing a general body of informed consent forms on considered techniques and situations, to be offered, nationwide to physicians.

2. Competence of critically ill patients is normally decided by ICU physicians.

3. Surrogates (mainly family) are regulated by law, with a clearly defined hierarchy: 1) wife or husband; 2) parents (first if patient is not married); 3) brothers according to age; 4) children if age of majority has been reached, and so on. If patients are not considered competent, surrogate authorization is a valid alternative.

4. Research other than with drugs does not require informed consent. This is only requested (mandatory by law) when a controlled clinical trial with new or old drugs is conducted. Epidemiologic research does not require informed consent.

#### Sweden

1. Clinical research is not regulated by law, but there is a professional consensus regarding its ethical basis created in co-operation between different governmental and academic bodies. Informed consent is mandatory but until now written documentation has not been demanded.

2. The physician in charge of the Intensive Care Unit and the referring physician should agree whether the patient is competent to give a valid informed consent (we share the responsibility for the patient).

3. There is no official surrogate, but the closest next-of-kin may consent or refuse if the patient is incompetent.

4. If informed consent cannot be obtained no study can be performed.

#### Switzerland

1. The basis for informed consent are given by the law (a number of cantons have a law that regulates clinical research) and by the Guidelines for Experimental Research issued by the Swiss Academy of Medical Sciences (17 November 1981, 11 May 1989). In university hospitals, the basis for informed consent are also given by the Committee for Ethics in Research involving human beings. In addition, the guidelines for good clinical practice are also taken into account.

2. The attending physician evaluates if the patient is competent to give a valid informed consent. This question is often raised and debated by the ethics committee, depending on the type of patients included and the protocol submitted.

3. It is possible for the patient to delegate consent to a surrogate but this is very rare. The next-of-kin or other family member is frequently considered to be the surro-

gate. If no family member is available, the Chief Justice or his representative is usually contacted and he names a temporary surrogate who is frequently a member of the medical team responsible for the clinical care of the patient.

4. It is very difficult to do research without informed consent and in general the ethics committee does not give its permission. However, when it does happen, investigators use one or two witnesses, in general a nurse or other allied health care personnel, to decide if inclusion in the protocol can be considered.

#### The Netherlands

1. The informed consent is regulated by the Ethical Committee of the hospital and is required for all studies. The patient or when incompetent his representative receives a written document explaining the goals, benefits and possible risks of the study. Drug-related research must meet the guidelines of good clinical practice. The patient is completely free to decide and can withdraw from the study at any time. In the near future The Netherlands will most likely follow the general rules designed by the EEC.

2. The patient is competent if he/she is able to understand the meaning of the written document and if he/she is considered able to decide freely. The judgement of competence is assessed by the doctors responsible for the patient and not by the investigators.

3. The surrogate is not officially nominated. In some hospitals it is the spouse or the close relative. It is permitted

to ask the next-of-kin if he/she is willing to decide on this matter. A signature is not always required but the approval has to be documented in the patient's chart.

4. Research without informed consent is not allowed.

#### United Kingdom

1. Consent is required to by law in order to defend oneself against a possible charge of assault; this is a general law, not specifically related to medical practice. It is also good clinical practice. Consent does not have to be written, the patient who voluntarily submits to a procedure may be deemed to have consented. However, written consent is a strong incontrovertible protection when major procedures are performed.

2. It is usual for the attending doctor to decide whether a patient is competent to give informed consent.

3. In law, a minor (under 18 years of age) may have a surrogate (parent or legally-appointed guardian) for consent purposes, but adults are either competent, or should be treated in their best interests by the attending doctor. However, in the case of an incompetent adult, it is good practice to get the agreement of next-of-kin; this may be called "assent" rather than "consent".

4. Research which must be performed without prior consent because of an emergency situation would be acceptable if the local Ethical Committee had accepted the protocol, and would usually (but not invariably) request consent or assent to be obtained at the earliest opportunity afterwards.

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