

Informed Consent Guide

(revised version)

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**Bioethics Committee of
Catalonia**

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Presentation

Both the General Health Law (1986) and the Law on Health Planning of Catalonia (1990) clearly opted for fostering a health-care model focused on the humanisation of health care services that would maintain the utmost respect for the dignity of the individual and individual freedom. In this model, the greater degree of participation of the individual is based on the preliminary information required to help people to reflect upon and evaluate the convenience of undergoing the health-care actions proposed to them.

The in-depth development and consolidation of this health-care model, which addresses the will and desires of patients to a greater extent, requires some time to mature so as to materialise an ensemble of specific practices.

For some time now, all the health centres in Catalonia have worked towards decidedly implementing the so-called **informed consent** (IC), and in many of them there has been debate and reflection among health professionals as to the introduction of a formal but ultimately real practice that will make a marked contribution to changing habits and attitudes. The former Advisory Bioethics Committee, now the Bioethics Committee of Catalonia, contributed to this debate and reflection by promoting different forums and working days that concluded with the first edition of the *Guide for recommendations on informed consent* (1997).

Following the logical train of thought which imbues all legal standards with bioethical considerations, the reflection and recommendations contained in this guide were taken into consideration by the legislation enacted in the form of Law 21/2000, of December 29, by the Parliament of Catalonia *on the rights to information on health and the autonomy of the patient and clinical documentation*. This Law also gives more concrete form to the Convention on biomedicine and human rights of the Council of Europe, "*for the protection of human rights and the dignity of human beings with regard to the application of biology and medicine*" which includes, for the first time ever, the possibility of making an advance directive as the continuation of

the IC, and on which a guide of recommendations was also published by the Bioethics Committee of Catalonia. Finally, and more recently, the *Citizens' charter of rights and duties* in health and health care also emphasises respect for the autonomy of patients exercised through informed consent.

This new legal and programmatic reality led the Bioethics Committee to address the need to review the guide and leverage the opportunity to reiterate the need for this consent to be given properly, without losing sight of its ultimate finality, namely to involve the patient in the decisions and responsibilities that affect him, and not that of preventing it from being transformed into a tool for the promotion of a defensive medicine that reduces the professional's responsibility when indicating or acting. The aim is, and this is worth repeating once more, that the legal character of consent will not replace the possibility of communication, dialogue, understanding and shared decision-making which are the cornerstone of health care.

The Bioethics Committee of Catalonia believes that it is necessary to continue to insist upon and go deeper into the ethical nature that must drive health-care relationships, beyond the indispensable legal framework. This is why I would like to thank all the members who with their voluntary and selfless work contributed to writing the first version, as well as the members who have made a fresh effort to adapt it to the times.

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1. Introduction. Definitions and objectives

Informed consent (IC) must be understood as the acceptance by a competent patient of a diagnostic or therapeutic procedure after he has been suitably informed in order to become freely involved in the clinical decision. The basic requirements are: freedom, competence and sufficient information. Therefore, it must be seen as the result of the clinical relationship, based always on two irreplaceable and unmistakable cornerstones: trust, and the more or less complex process of information. It must foster understanding of the procedure proposed, state what it comprises, possible alternatives, opportuneness and expected results (with benefits, sequelae and risks), and be geared towards reaching a decision, be it choice, acceptance or rejection.

The existence of informed consent is recorded by the signature of a document which must be properly explained first. In fact, when the patient signs the document of consent, he is freely consenting to undergo a procedure on which he has been given suitable information, the information he needs to take a reasoned decision.

Professionals have to help to decide flexible ways for implementing informed consent. Thus, a collective reflection is called for at all levels: health, legal and social. This reflection must define the basic concepts first to avoid confusion between them. The different values involved should also be considered, particularly the needs of the patient, while legal realities should also be clear, the different readings thereof and their possible consequences. However, first and foremost, we need to go deeper into the true nature of clinical communication, and its difficulties, because failure to analyse the real complexity may lead us to oversimplify matters.

2. The right to information and to informed consent (IC)

The right of each and every one of us to be informed and to give or withhold our consent in any health situation stems from the basic right to have our personal autonomy respected in a situation of disease. For this reason it has evolved as a legal obligation in most countries throughout the second half of the 20th Century. In Spain it was expressed in Law 14/1986, of April 25, the General Health Law (LGS). As of this law, awareness of this right has evolved, with the development of what is now known as informed consent in bioethics and in clinical practice.

Here, particular mention should be made of the relevance of the Convention of the Council of Europe "for the protection of human rights and the dignity of human beings with regard to the application of biology and medicine: Convention on the Rights of the Human Being and Biomedicine " (CDHBM), in force since January 2000. In the wake of this convention, the new Law 21/2000 was enacted by the Parliament of Catalonia, governing the right to information, confidentiality, the granting of consent, including advance directives, and access to Clinical Documentation.

Thus, the following legal framework must be considered in the implementation of IC in our setting:

- Spanish Constitution articles 9.2. (right to freedom), 10.1. (on the dignity of the individual), 15 (on the right to life and to physical and moral integrity).
- General Health Law article 10, section 4 (right to give authorisation to be part of an educational or research project), 5 (right to receive information in understandable terms), 6 (right to choose between the options proposed) and 9 (right to refuse treatment).
- Convention on Biomedicine and Human Rights of the Council of Europe for the protection of human beings with regard to the application of biology and medicine, article 5 (the impossibility of acting against a person's will), 6

(protection of the disabled), 7 (protection of persons with a mental disorder), 9 (consideration of advance directives/previously expressed wishes), 16 and 17 (protection of research subjects) and 19 and 20 (consent for the extraction of organs and tissues).

- Law 21/2000, by the Parliament of Catalonia, on the right to information on health and the autonomy of the patient and clinical documentation, from which we shall cite *in extenso* the articles most related to informed consent.

Art. 2 Formulation and scope of the right to information

- 1. People have the right to know all the information obtained about their health. Nevertheless, the wish of a person not to be informed must be respected.*
- 2. Information must be part of all health-care actions, it must be given in an understandable way, be true and suited to the needs and the requirements of the patient, to enable him to take decisions independently.*
- 3. The doctor in charge of the patient must guarantee compliance with the right to information. Responsibility in the information process must also be taken on by the health-care professionals attending the patient or who are administering a certain technique or procedure.*

Art. 3 On the holder of the right to information

- 1. The holder of the right to information is the patient. The people in some way linked to the patient will be informed to the extent expressly or tacitly expressed by the latter.*
- 2. In the case of incapacity of the patient, the information must be given to his representative.*

3. *When the patient, according to the criteria of the doctor in charge of his health care, is unable to understand the information due to a physical or mental condition that renders it impossible for him to understand his situation, the relatives or related persons will also have to be informed.*

Art. 6 On informed consent

1. *Any action in the sphere of health requires the person affected, having been duly and suitably informed, to give his specific and free consent, according to the provisions of article 2.2. This consent must be given in writing for surgery, invasive diagnostic procedures and generally speaking when procedures involving known and foreseeable risks and drawbacks that may impact the health of the patient are to be performed.*
2. *The document of consent must be specific for each case, although general information sheets may be attached. This document must contain sufficient information on the procedure in question and its risks.*
3. *The person affected may freely withdraw his consent at any time.*

The *Charter of rights and duties of citizens in health and health care*, approved in June 2001, sections two and five, also provides different specifications on IC.

Following revision of this guide, the "*Basic Law regulating the autonomy of patient and rights and obligations in information-specific questions and Clinical Documentation*", which follows the spirit of the Catalan Law 21/2000, was approved in the Chamber of Deputies on October 31, 2002 .

3. Ethical aspects of IC in clinical communication

The clinical relationship lies at the heart of all health care. This relationship has been based historically on the predominant value of welfare, regarded as the search for the benefit of the patient, and had been applied according

to a paternalistic scheme in which only the doctor decided; he did so on the patient's behalf, although without imposing his own criteria. This model has fallen into crisis recently for many reasons: particularly because the patient is now regarded at all times as an adult empowered to act autonomously in decisions that affect him. This is the embodiment, in the health area, of the human rights of the individual. Some changes in the structure of the health care services have rendered the relationship more complex; unforeseeable and rapid advances have increased options and made decisions more difficult to take, and citizens have become increasingly more demanding in terms of their rights. These and other changes have led to a change from the previous model, to another one where more values are at stake, such as equity (according to which everyone is entitled to the same considerations in the event of disease) and personal autonomy (or in other words, the right to be respected as an adult who has to decide on questions affecting him, even if he is ill).

These new values are embodied in the acknowledgement of new patient rights. Thus, the obligation to secure freely given consent before any action and the right to information of each patient promotes the exercise of growing autonomy. In this way, society has aimed to promote the eclosion of these new values, which, with the help of the law, must be brought into the clinical relationship, going beyond welfare. To summarise, the law manifests the patient's right to information and to anything that is known about him, and to give his consent to what he is offered. Therefore, it follows that the professional has the obligation to make his knowledge available to the patient at all times, and not just to secure consent; and he is likewise obliged to submit a reasoned proposal the patient may or may not accept, and which will be recorded in writing. The standard IC aims to make sure that the patient has had the opportunity to exercise his right to self-determination.

But the law cannot go much beyond these these basic generalities. It reminds us of basic rights that cannot be infringed, but does not address the specific needs of the patient. It aims to make progress in fostering new values, but the way they are to be applied cannot be reduced to a legal

standard. What is more, merely applying the law with rigid general forms may violate other obligations that professionals have towards patients, such as to help them to adapt to the new reality, overcome fear or increase their hopes and confidence; and this is why a personalised and prudent analysis, or in other words one that is tailored to each situation, is indispensable, if each person's needs and preferences are to be respected at all times.

The aim must be for clinical information to adapt to the needs of each patient, taking into consideration that such needs may vary from one person to another, and from one moment to the next. The patient wants to have the information at his disposal without fear of things being paternalistically withheld or over-defensiveness. The virtuous professional is the one who, while understanding every patient's right to decide, also discovers and respects the needs of each one of them and adapts; not he or she who imposes information on someone who does not want it or who does not need it. Therefore, to be useful to the patient, the good professional must be inquisitive to discover personal values and limits and subsequently respect them. Oral information permits this necessary flexibility. A way must be found, with the help of everyone, for written information to make this possible also. The law can never predetermine this practical prudence, as it must be left up to the ethical assessment of each professional. More than anything, IC is an ethical question.

The information must be true. Lies cannot be justified: they are an abuse of power, a concrete and irreversible path, and one which can be avoided. It is not a question of telling white lies, but rather of finding charitable ways of reaching the truth. The materialisation of truth must be specific or individualised; it is therefore a process that always takes multiple forms where the professional has a certain leeway, postponing and expanding upon true information.

Information is not given in a single moment or deed, it is an oral process, a dialogue, and consent for a procedure must be a coherent part of that. In actual fact the basic consent, ethically speaking, is always oral. No read and signed document can ever replace dialogue. For many procedures, and

many patients, information and procurement of consent may be easy and rapid, while it may require some time for other patients or other procedures. The patient often needs time to accept an unpleasant piece of information with less pain, take it in and then convey doubts, reticence or formal questions. Very often an informative evolution, an evolutionary oral process, is required.

Furthermore, consent must be given freely, without coercion. It is true that some of the help many patients may need is in decisions, advice and perhaps even persuasion. But it is convenient to distinguish between persuasion and coercion, since in the latter the patient's freedom to decide is not respected. The patient must have opportunities to get engaged in the decisions to be taken and must be able to do so on his own terms. The signature of the IC document is an opportunity guaranteed by the law. Thus, the signature of the IC document must be seen as an occasion where this right has been guaranteed. However, not only is it a question of a legal guarantee, as it may even constitute a stimulus for the participation and involvement of the patient in decisions, as far as he wants, and of the professional in the changing needs of each patient (some will need many details, others fewer, others will prefer to waive their right to take decisions and delegate this right to others).

Therefore, besides being a legal requirement, IC should also be seen as a chance for doctors to discover the real needs of each person. And signature of the document thus becomes a chance to formalise the clinical dialogue process: to reconsider the information the patient has, that he needs, his understanding, his difficulty in relating it to his projects, doubts and to gauge his fear. Consent is not just a reason for sharing decisions, it must be the fruit of a shared dialogue.

For all these reasons, an effort must be made for this communication dialogue to mark the form, quantity and limits of written IC, and not the opposite, as defensive medicine might seek to do, giving priority to needs other than those of the patient.

4. Dialogue for promoting IC

Just as IC is a chance to analyse the needs of each patient, fostering its use is also a chance to analyse the peculiarities of each centre, each service and each professional, before getting bogged down in norms.

Therefore, besides guaranteeing the autonomy of the patient as a health-care quality requirement, fostering IC will enable us to go deeper into the analysis of the complexity of the clinical relationship. And in this regard, the opinion of the clinical professional is basic; we must avoid seeing it as control or as a purely defensive requirement.

The need for this dialogue among clinical professionals is so patent that the Administration has taken it into account when trying to solve this question and, abandoning a certain impatience, has opted to promote progressive and dialogue-driven awareness-raising by means of a symposium promoted by the DHSS, special Working Days by the Instituto Català de la Salut and a task force of the Advisory Bioethics Committee of the DHSS. In these experiences, the decision was taken to stimulate reflection on the implementation of IC and to avert bureaucratisation. At the same time, the opportunity to draw up a guide to help the general base of CI and its limits and problematic cases was detected. Over these five years, almost all the centres in Catalonia have set up health-care ethical committees (CEA) or ad hoc commissions for IC, and the existing legal framework dating from 1997, the year in which the aforementioned guide appeared, was improved. The need to continue to analyse the practice of informed consent still exists, and was the driving force behind this update. In fact, all these initiatives aim to promote dialogue and avoid precipitation.

- It is necessary to foster the responsibility taken by the patient in clinical decisions promoting the implementation of the IC document.

- Professionals should be made more aware of this practice, which offers the aforementioned advantages, and which can be seen as a chance to improve quality.
- Plans based on an effort to increase awareness and understanding of the question in its real terms, avoiding excessive bureaucratisation, are called for.
- The information must be pitched to the needs of the patient and procedures, avoiding unnecessary exhaustiveness.
- The written information must be as personalised and intelligible as possible, avoiding the defensive use of the documents.
- Preliminary dialogue must be fostered, and should not be replaced by documents.

5. Information for IC

A. The competent patient must be able to access the information on his process at all times and be able to give his consent or refusal, with total freedom, in a medical situation.

B. Ethically, the quantity, form and pace of the information and even the requirements pertaining to the signature of documents, have to be suited to the needs of each patient, and a suitable action framework is therefore required.

C. The information has to be seen as a process, particularly oral, in which professionals, taking into account the patients' interests, peculiarities and wishes, as well as what is being proposed to them, decide the pace, quantity and form in which it is offered, to enable patients and relatives to take a decision honestly and freely.

D. Doctors must have sufficient professional skill and judgement to recognise the limits marked by the patient and adapt to the peculiarities of each case. It is not a question of burdening patients with all the available information (diagnosis, prognosis, all possible risks, etc.) unless the patient so wishes, as this could be counterproductive. The aim is for the patient to

have the information at his disposal, totally above board and no impositions.

E. The law does not define the content and the scope of the information to be given to patients before signing the consent. At this moment patients must be able to understand the overall chances and risks involved in what is being offered so that they can take part in the decision. Therefore, the information (particularly oral information) should comprise the following:

- Advantages of the operation versus other possible alternatives.
- Certain or very probable consequences of the operation that are of relevance to the patient. This includes any psychological and emotional consequences of the operation.
- Typical risks, those inherent to the procedure.
- Personalised risks.

While in the future more patients may be expected to wish full information, those who do not must be duly considered and their wishes respected. In these cases, the information the patient does not want (a wish that he will have expressed verbally) must be conveyed, unless prohibited by the patient, to the family or his immediate care-givers. Due consideration must also be afforded, when providing information, to cases in which decisions are not taken individually but rather by a group, such as the relatives. If the patient has appointed a surrogate or empowered representative, the professional's reports must be addressed to this person.

F. The hermetic nature of medical terms must not be allowed to stifle true communication. In this regard, clarity is preferable to exhaustiveness.

G. Besides giving information, any questions must be answered, concepts not understood cleared up, doubts dispelled and help given in conditions of indecision. Time should be allowed (to pose queries, as the case may be) for the information received to generate doubts, and any indecision or fear to be expressed. Very often this type of issue is expressed by patients when they later say they were not properly informed.

H. The documents must provide for minimum information sections (mentioned in the chapter following this Guide) that must be properly completed for each situation.

I. In all cases in which a patient has given his written IC, he will be entitled to receive a copy of the document.

K. Information given prior to consent must be given sufficiently in advance and in a setting that is conducive to a well-deliberated decision and, as the case may be, for consent to be withdrawn.

6. IC Documents

As a first measure, and for the sake of prudence, the Symposium of the Department of Health and Social Security (May 1995) and the Working Days of the Instituto Catalàn de la Salut (June 1995) recommended the elaboration of a basic and open document, which in our opinion is still an advisable proposal. It is a general document that has to be completed for each patient individually and which specifies the proposed diagnosis or specific therapy and its characteristics. This document may be complemented by other, more comprehensive, information, written beforehand.

The documents must refer to the specific procedure (operation, technique, exploration) and may omit other unnecessary questions, particularly any that have not been addressed in the dialogue process.

The basic document, common and open, has the advantage of being adaptable to procedures, including any that were not initially envisaged, and permits the daisy-chaining of procedures targeting the same end (anaesthesia and surgery or blood bank). This avoids a glut of documents, and is beneficial to the patient.

The open document, which doctors must complete for each patient, is very useful when the information needs to be personalised and in cases of diagnostic and therapeutic techniques which are not strictly regulated or

standard. Therefore, the open document may be indispensable in some specialities (general surgery, gynaecology, urology, etc.).

The closed or standard documents, already drafted, are useful in certain techniques, and where the person requesting the signature will not be performing the technique (endoscopic explorations, radiology, transfusion, etc.).

A. Open and basic, personalisable IC document

The open and basic document, which may be common to many procedures, should never be general in scope, as it must always specify the proposed procedure and its specificities. It must contain the following minimum sections, which must all be completed:

- a. Identification of the patient, the doctor indicating and requesting the consent, and the medical services to be carried out.
- b. Description of the procedure(s) proposed, the objectives pursued and the alternatives.
- c. Description of the consequences that could be of import to the patient (colostomy, in some cases scarring, for example).
- d. Typical or inherent risks in the procedure: those that present with greatest frequency or which, albeit rare, are of major importance. This type of information is the most controversial and where the concept of suitable information established by the Convention of the Council of Europe must be applied most strictly. Certain occasions may require a vast amount of in-depth information, because the patient so requests or because a small benefit and high risk render such an approach advisable. On other occasions - for example, by delegation or verbal waiver by the patient, out of manifest anguish or emergency- and if the indication is clear, the information may be less exhaustive, but it must be sufficient, understandable and true to the patient's situation.

e. Personalised risks according to the problems of a specific patient, his prior condition, or serious risks, with profession or life expectancy taken into account.

f. Consent for changing approach or technique, provided that it is to solve the specific problem for which consent is being or has been given.

g. Information on the right to accept or reject the treatment proposed or withdraw a consent already given; and information on the patient's right to explain his own limits (for example, the patient does not want blood transfusion or total mastectomy).

B. Information documents which have already been written

Besides the open, basic and personalisable document, common to many procedures, it is a good idea to draft written information specific to determined techniques, and which should refer to the seven points of the previous section.

They can be discussed, agreed upon and drafted by groups of professionals or by scientific societies. Initially, they will be more comprehensive: they may detail the discomfort involved and the care required, they may contain more positive information (on advantages and the good results expected, etc.), although the information they contain cannot be so personalised. Care must be taken with the use of percentages that say very little to the profane, and technicalities should be avoided. And it should also be remembered that when talking about risks or results in general, reference must always be made, as far as possible, to reality, rather than to unfamiliar texts.

These information documents (well-made, and which may even include drawings, video tapes, etc.) should be given well enough in advance of the procedure (and the consent) to allow the patient to give due deliberation to the decision.

To be used alone, information documents which have already been written must contain sections that can be filled in individually (semi-open).

They will preferably be attached to the open documents in which, in the relevant section, a reference to the written or visual information attached to the document may be placed.

7. Formalisation of IC

7.1. The doctor in charge and the health-care team

Modern medicine is about teamwork. To a large extent, the clinical relationship has lost its uni-personal character, since hospitals now have numerous people working on patients' health problems (medical and nursing staff, social and other workers). However, patients identify a small group of people who they see as responsible for their health care. Article 2.3. of Law 21/2000 of Parliament specifies this very clearly, stating that:

“The doctor in charge of the patient must guarantee compliance with the right to information. Responsibility in the information process must also be taken on by health-care professionals attending the patient or administering a certain technique or procedure.”

This “doctor in charge” must be the main agent in the information process, in both diagnosis and treatment, and must inform patients on the procedures advised. It is precisely in this area of relationship where the IC process takes on greatest meaning.

The information process begins at the outset of the relationship and culminates in the formalisation of the IC document. In the course of this process patients will be furnished with verbal or written information, either through the doctor in charge of their health-care or by other members of the team, who must also make sure that the information is coherent and consensus-based.

On other occasions, the professionals prescribing the techniques and those who perform them will have to reach an agreement depending on the characteristics of the examinations to be carried out (interventionist radiology, potentially serious risks, procedures that have to be carried out in other centres, etc.): ranging from indication and action protocols until the way the consent is obtained. And this agreement must apply, if necessary, to professionals from different health-care centres or levels. For example, someone who formalises the IC written for a diagnostic procedure may be a person who is not performing it; however, he may present a document for signature with information previously agreed to with the person performing it. Despite this, the performer and the person who is most conversant with the technical details is also responsible for completing the information later.

The health information furnished on entry at an institution must state that it is educational, and this means that the health-care team includes trainees and even students, who nevertheless are also monitored by a fully-trained doctor who is responsible for them.

7.2. Primary Care

Although hitherto IC has been developed in the hospital setting, primary care professionals are involved in the task of reaching the basic objective of IC, namely to promote the autonomy of the patient and to comply with the requirements of the right to information.

The primary care offices provide information on many diagnostic and therapeutic procedures, and it is often the actual doctor who requests these procedures. Here are some in which written consent is indispensable: radiological tests with contrast, ambulatory surgical interventions and therapeutic endoscopies.

The doctor requesting the test is best suited to give any oral and written information required. By virtue of their accessibility, confidence, knowledge of the patients, etc., doctors and nursing professionals in primary care play a key role in establishing and disseminating what might be termed the culture of IC, not only by using it their procedures, but also in fostering and

supporting the use of IC in hospitals, since the actual patients are users of these services.

7.3. The nursing professional and IC

The nursing staff deal with the care needs of healthy and/or sick persons, from a global standpoint. The interpersonal relationship between the user/patient and the nurse is fundamental, and with this help-driven relationship, aims to develop communication with a therapeutic and care-targeted objective.

Nurse, by virtue of their professional responsibility, must guarantee compliance with the CI and, in view of their regular and direct contact with the patient, eventually understand what the person is like, his family environment, feelings, emotions, doubts, knowledge and degree of understanding; nurses are therefore in possession of knowledge that might be necessary for the doctor to be able to give information and request consent in the most suitable way.

Information on diagnosis, prognosis and the evolution of the disease is the responsibility of the doctor, although the nursing professional must help to clear up any doubts the patient may have and must be attentive to the patient's request for information and help him to get it when he cannot provide it as it is medical information. He must also reinforce medical information in aspects related to nursing care, e.g. the administration of medicinal products or preparation for diagnostic or surgical tests.

In the informed consent process the nursing professional must collaborate with doctors to evaluate the patient's degree of information and understanding, as well as his level of competence to take decisions. This collaboration is necessary, particularly in situations of conflict in which the patient cannot think straight, fails to take a decision or reacts unexpectedly. He must always remember that the objective is to help the patient to understand the information on his health problem and the necessary therapeutic measures; thus, and even in cases of relative incompetence, information will be a health care priority.

Respect for the right to patient autonomy obliges the nurse to furnish him with all the information necessary so that the user can also give his consent for care-related activities. Although this consent will be oral in most situations, it is nevertheless an important code-of-conduct requirement.

Dialogue with the doctor in charge of the patient is indispensable and is the responsibility of both, nursing professional and doctor, in order to conduct a coordinated action.

8. Limits of IC

There are limitations in the practice of informed consent in a medical situation. These were already provided for by the General Health Law of 1986, article 10.6. (Risk to Public Health, emergency and incapacity), although they are better specified in Law 21/2000, which distinguishes between the exceptions to the requirement of obtaining it, and moreover, situations in which it should be obtained by surrogates:

"Article 7, Exceptions to the requirement of informed consent and the granting thereof by a surrogate

1. Informed consent is not required in the following eventualities:

- a) When there is a risk to public health, if required for health reasons in accordance with the provisions of the applicable legislation.*
- b) When in a situation of serious immediate risk for the physical or mental integrity of the patient it is not possible to secure this authorisation or that of his relatives or the persons in some way linked to him.*

In such cases, the interventions that are indispensable from the clinical standpoint for the health of the affected individual can be carried out.

2. The following situations of surrogate consent are provided for:

- a) When the patient, in the opinion of the doctor in charge of his health care, is not able to take decisions as he is in a physical or mental condition that renders it impossible for him to understand his situation,*

consent must be obtained from his relatives or persons in some way related to him.

- b) In the case of legal incapacity, according to article 219 of Law 9/1998 of July 15, on the Family Code.*
- c) In cases of individuals interned for mental disorder, who meet the circumstances provided for in article 255 of Law 9/1998, of July 15, on the Family Code.*
- d) In the case of minors who, if they are neither intellectually nor emotionally competent to understand the importance of the operation for their health, the consent must be given by the representative of the minor, once the latter's opinion has been heard, if he is above the age of twelve years. In the other cases, and particularly in emancipated minors and adolescents above sixteen, the minor has to give his consent personally.*

Nevertheless, in the legal cases of abortion, clinical tests and assisted human reproduction techniques, generally speaking the legislation civil on majority of age must prevail, and, as applicable, the specific rules or regulations.

- 3. In the eventualities defined in letters a), b) and c) of section 2, any interventions that are indispensable for the individual affected from the clinical point of view may be carried out.*
- 4. In cases of surrogate consent, the decision must be as objective and as proportional as possible to benefit the patient and to respect his personnel dignity. Similarly, the patient must participate as much as possible in decision-making.*

This is as far as the law goes. However, there are other limitations pertaining to informed consent which have been recognised in bioethical literature and even in some laws, such as waiver or delegation, therapeutic privilege, or not undertaking or withdrawing a futile treatment.

8.1. Risk to public health

The Organic Law 3/1986, of April 14, in matters of Public Health, makes it possible to take measures against a person's will in two cases:

- a) For emergency health reasons.
- b) Out of need.

The measures that can be taken pursuant to this law are health examinations and obligatory treatment, obligatory hospitalisation, health controls, vaccinations, etc.

These measures, limiting the fundamental right to freedom, must be used exceptionally. According to the aforementioned law, only the health authorities can apply these measures and must justify the emergency and the need. However, there is quite a common opinion which holds, when this type of measures are taken against general opposition, that it is advisable to take the matter to the judge so that the Administration of Justice, using the reasons alleged by the Health Administration, will authorise it.

8.2. Capacity and competence

It is necessary to distinguish between the legal capacity of a citizen and the de facto incapacity to decide (sometimes called "competence") he may suffer from at a given moment.

From the legal standpoint, incapacity is typical concept in civil law which has consequences in the different areas of life (use of the rights and assets of the individual). In this regard, minors are incapacitated, as well as other individuals explicitly incapacitated for other reasons.

Article 200 of the Civil Code makes the following provisions:

'Grounds for incapacitation include persistent physical or mental diseases or deficiencies that prevent the person from acting for himself'.

Moreover, article 201 indicates that:

"Minors may be incapacitated in the event of a prevailing cause of incapacitation which may reasonably be expected to persist after majority of age".

It is evident that in such cases of legal incapacity, the legal guardian will be the surrogate for the purpose of granting consent. Only if this is not possible should the doctor use the principles of welfare as his guide and take the most objective and proportionate decision that he can.

In the other cases of legally capable patients, 'competence', or de facto capacity, is taken to mean the patient's ability to understand the situation and take a decision. This is variable and depends on several factors: mental, degree of pain, drunkenness, depression, anguish or bewilderment. The more important the decision, the greater the risks and the fewer the benefits involved, the greater the competence the patient must show. The doctor has to assess this competence and at the same time help him to raise it if necessary: allaying his fears, giving him time, reformulating the information, etc.

The competence of a patient must always be presumed, and on no account can the formalisation of personalised consent be foregone, be it acceptance or refusal. In the delicate process of analysis of the competence of a patient, it may be advisable to seek the help of third parties and even of a CEA. In any event, conflicts of this type must always be duly recorded in the clinical history so that they can be deliberated afterwards.

Advance directives, expressed by the patient beforehand, when he was competent, and particularly if documented, must be taken into account before a decision is taken (art. 8 of Law 21/2000), either if the document is in the clinical history or if it is furnished by the representatives or can be ascertained by checking a register. If there

is no advance directive, consent must be secured from the appointed representative or the patient's family. Only in cases of impossibility may the doctor act according to medical criterion.

8.3. Emergency

In the case of imperious emergency the formalities for obtaining informed consent may be very limited. It may be necessary not to waste time in order to start treatment, in which case IC may be limited to obtaining an oral consent after simple information has been given, if this is possible.

If the previous circumstance is not possible, the information may be postponed until circumstances so permit, and the relatives and companions of the patient can be informed.

Emergency cases often permit an IC, even a written one. It is true that emergencies often cause great anxiety, with a compelling need for help that is hardly conducive to a progressive information process; elaborate information can sometimes be painful and lucidity of understanding and competence to take a decision may be impaired in certain people in emergency situations. In these cases, without foregoing the signature of an informed consent document, the information would have to be limited to that which really helps to weight up risks and benefits, simply and realistically, with the professional's help, in the form of advice and even persuasion (not coercion). Evidently, the patient must be offered, orally and explicitly, the possibility of knowing, in greater detail and more extensively, other possible risks so as to adapt to his wishes.

The patient's will, even his refusal to undergo a vital treatment, must be respected, after making sure that the patient is clearly competent and there is no doubt that he has taken the decision freely. In such cases it is advisable to ask for the refusal in writing, check with the family and seek the opinion of a third party.

If the patient is unconscious, and also in an emergency, the limits expressed in the advance directive document must be taken into consideration when formalising the IC with the representatives.

8.4. Waiver or delegation

The right to be informed, like all rights, can be waived, and consequently the will of the individual who does not want to be informed should be respected, as is also provided for by Law 21/2000.

The Convention of the Council of Europe on the Rights of Human Beings and Biomedicine expressly recognise the possibility of this waiver in the following terms:

“Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed”.

The Convention, however, also establishes that this waiver may be limited in cases where it is advisable to protect the rights of a third party or society (for example in the case of infectious diseases).

Moreover, in our setting people frequently delegate the right to decide to another member of the family or even to the doctor, even if he does not do so in writing, and in these cases it is usually accompanied by waiver, perhaps partial, of the right to information, or the refusal to continue to be informed as of a certain moment. Such a decision may be autonomous and express the patient's own wishes, and must therefore be respected and harmonised with the formalisation of the mandatory informed consent.

The professional must make an effort to get close, albeit with caution, to the patient's decision and not to take it for granted in advance. He must tell him that the information will soon be provided in order to have an idea of how the patient will take it. He must actually tell the patient that he needs information to be able to take a decision on the options to be taken in order to adapt to his preferences. This attitude ethically distinguishes between a delegation by the patient and a unilateral doctor's “therapeutic privilege”.

Nevertheless, oral or written consent, when necessary, cannot be omitted, even in cases of delegation of decisions or the wavering of information; it is a different matter if the quantity of information provided in the mandatory sections is scant, in keeping with the wishes of the patient. In such cases (unless expressly prohibited) more comprehensive information will have to be furnished to his representatives, as they are presumed to be his delegates, and therefore the decision makers.

8.5. The “therapeutic privilege”

According to what the doctrine calls “therapeutic privilege”, the professional, on the basis of the patient’s data and the benefits expected for him, may avail himself, either on his own decision or with the complicity of the relatives – of the capacity to conceal all or part of the truth. This stance does not stem from an autonomy defended in the process of dialogue, as is the case of the limit expressed before in the delegation of the decision and in the refusal to receive further information; in this case, there is no opportunity for free expression by the patient. While it may be considered as a possibility, this situation has to be seen as very exceptional, since it may lead to systematic paternalistic abuse. If it is used, it must be reasoned in writing in the clinical history, thus allowing for the possibility of verification by third parties. It must be emphasised that not even the “therapeutic privilege” can justify a lie.

9. Special situations

9.1. Clinical tests and innovation

Although this Guide does not refer specifically to clinical trials, a few brief notes on this question are provided below. The regulation of clinical trials stems from the need to strike a balance between the different rights that may collide. Indeed, research is necessary for science to make progress and for new cures to be found for diseases, but this must never contravene the rights of the individual.

The Law applicable to clinical trials –basically Royal Decree 561/1993, of April 16, which establishes the requirements for the conduct of clinical trials with medicinal products - contains a series of provisions for IC which are of paramount importance in this setting. In this regard, the consent of the interested party must be secured before the trial can go ahead. This consent must be given freely, and the person must have manifest competence. It must be obtained in writing, although if for any reason this were not possible it must be done in the presence of witnesses. In any case, it must be duly documented and written in understandable language.

Before giving his consent, the subject that will be involved in the trial must have been informed exhaustively by the health professional conducting the research on the nature, importance, scope and the risk of the trial. The professional giving the information must make sure that the subject has understood this information. The trial subject may withdraw his consent at any time without having to account for his decision.

In the case of minors and the incapacitated, the consent must always be given in writing by the legal representative. Nevertheless, when the conditions of the subject so permit, and when the minor is twelve years old or more, he shall also have to give his consent. The Royal Decree 561/1993, of April 16 particularly protects the rights of minors and establishes that cases involving minors must be brought to the knowledge of the Public Prosecutor before the trial is performed. In the event of an emergency in the application of the treatment that renders it impossible to have the subject's consent, the Clinical Investigation Ethical Committee must be informed.

In fact, both the Law on Medicinal Products and the Royal Decree 561/1993 attribute fundamental importance to IC. The Royal Decree contains an annex, namely number 6, which specifies the content and features an IC model.

In studies that require samples for genetic analysis, such samples may only be taken if the participant gives his consent after receiving appropriate

information. If the study is included in a project with broader objectives, a separate consent is required for the genetic study and for obtaining organic samples. Provision must be made for the results of the research to be made known to the participants if they are relevant for their health or their descendents. In any case, the participants must be informed of the implications of a possible waiver of receiving information on their genetic traits.

9.2. Childhood and adolescence

Normally, the person receiving the information and giving the consent is an adult who is capable of taking a decision. But minors can also find themselves in this situation of competence. In this regard, the current legal criteria consists of requesting the personalised IC of minors aged below 16 years.

Although a minor aged 16 would theoretically not be validly capacitated to give his valid consent, and it is his parents or tutors who have to take decisions in the clinical area, his maturity should nevertheless be deliberated and his opinion and need for respect and privacy be taken into consideration. Once this has been assessed on a personalised basis, in some cases the doctor could accept, following the spirit of article 7.2.d of Law 21/2000, his informed consent and his wish for confidentiality.

In any event, as of the age of twelve a child is regarded as being mature enough to be listened to, for example to postpone an operation that is not strictly necessary and he does not wish to undergo. On the other hand, in certain cases, in a serious health problem, if the doctor believes that the decision cannot be postponed, the criteria of the parents or guardians are not the most suitable for the interest and health of the minor, he may go to a judge to have the latter authorise the most suitable alternative.

9.3. Psychiatry and incapacitation

An added problem in giving information properly and to secure informed consent tends to arise in patients with serious mental disorders. The problem stems from the patient's temporary or permanent difficulty to reason properly when it is clear that his reasoning does not follow the logical principles which most people regarded as normal have. While fortunately, these cases are very infrequent, if the overall number of persons treated is taken into account, they are deserving of special attention. Apart from special cases, the recommendations on information and informed consent procedures may be the general ones used in medical practice. It is evident that the most acute problem arises with patients who do not wish to be treated or refuse hospitalisation when all evidence points to such medical measures being advisable or necessary, although the patient does not give his consent.

The preliminary recommendation normally taken into consideration in such cases is that which pertains to the danger or risk the patient's attitude may mean to himself or others. The consideration, which may not be easy to establish, is therefore based on the seriousness of the possible harm that may arise from failure to apply treatment. Normally, the difficulties for medical action and for establishing sufficient guarantees for the patient are manifest in two situations:

A) Non-voluntary hospitalisation

When the seriousness renders hospitalisation advisable, and which the patient does not accept, coercion for internment will have to be obtained with the authorisation of the judge, who will be aided by any medical information he deems convenient; in such cases the judge that has authorised the admission must revise the situation periodically.

B) Treatments

Surgical treatment and electroshock are usually the most difficult cases. In both cases all efforts should be made to secure the patient's consent. If the patient is unable to understand his health situation, consent will have to be

obtained from the family or the surrogate. In more complicated cases it may be advisable to request the opinion of the ethical committee, if there is one in the hospital.

9.4. Rejection of medical treatment

The patient has the right to reject medical treatment, even if it is vital for him. Law 21/2000 clearly states that: "*All treatment requires the freely given and specific consent of the person affected*". Therefore, if it is withheld the operation will not be performed. In this regard, article 10.9 of the General Health Law also establishes that everyone has the right to refuse treatment, barring the cases detailed in article 10.6, although in this case voluntary discharge must be requested.

Although the LGS states that the signature of a voluntary discharge document is mandatory, such a radical approach must be nuanced (as it is by the Charter of Rights and Duties of Users), since when a patient refuses treatment he must be offered alternatives, if there are any, and in any case he cannot be refused any care and palliative and support treatment he requires. In such cases it is advisable to have the patient express his refusal in writing.

9.5. IC and other cultures

A plural society like our own houses communities of persons with values, meanings, cultures and codes of communication which are different to those of the majority, and it is also a passing-through place for many immigrants. Nowadays, the movement of people with a different cultural and social baggage is now a burgeoning reality.

The health needs of these people have to be catered to, regardless of any social, religious, racial or economic differences. And despite these cultural differences, the right to information and to give personal IC can never be obviated.

Informed consent consolidates the clinical relationship and calls upon the professional to show greater sensitivity when the person being attended to comes from a different culture with different values and beliefs to his own. It is of paramount importance that he realise the need to be well disposed to dialogue. The possibility of discriminating and demoralising a patient who does not share our values is a risk that must be identified so that it may be avoided.

The attitude of the professional and the whole health organisation must be particularly open to perception of the needs of a patient who is not in his natural setting, but rather surrounded by different cultural meanings, perhaps even compounded by language limitations that may make it difficult for him to convey his feelings, doubts and decisions.

The concept of autonomy may take different forms, and information must therefore be adapted to personal needs. In some cases, delegation by the patient of the decision to his family or reference group may appear more forcefully or frequently, although we must make sure that this is what the patient wants. Another type of case may be that of the patient greatly used to looking after himself, who may require a much more detailed level of information than usual. Therefore, in the process of clinical information for securing IC from people from other cultures, special care must be taken in the following aspects:

- Be respectful towards different needs depending on the values of the patient and his reference group.

- Do one's utmost to explain the principles of the right to information and of the need to obtain personal consent, helping the patient to understand that he can determine the scope and the form.

- It is advisable for centres to be aided by cultural mediators or translators, depending on the number of different cultures or non-official languages in the setting.

10. Recommendations for promoting IC in health centres

Each centre must have a plan to promote informed consent with the initiative of the interested professionals. The plan should include the constitution of a multidisciplinary committee for clinical information and informed consent. If the centre has an ethical health committee (CEA) then it will perform this task.

This committee must have health-care doctors, nursing staff, personnel for the user attention units, members of the quality commission and research personnel, all appointed by the centre management. It is important that its members have a personal interest in this issue, and that one of them, who should preferably have minimal training in bioethics, should lead the dialogue and the training or formation of the group.

His specific functions must be:

- To draw up an open and basic personalisable document of informed consent for the centre, available to everyone.
- To detect the needs and the difficulties of each service or health-care unit, and particularly in which of the procedures used the signature of an informed consent document will be requested.
- Bring together different services or health-care units (for example, vascular surgery and angio-radiology), so as to decide the documents to be used, who obtains the consent and when and what procedures can have a common consent (for example surgery, anaesthesiology, blood bank, etc.).

11. List of procedures for which written IC is recommended

Each centre should have a list of the procedures in which informed consent will be necessary. The following procedures should be included, although the list cannot be regarded as being exhaustive:

1. Surgery with general or regional anaesthetic
2. Radiology with intravascular contrast, interventionist or with anaesthetic

3. Therapeutic endoscopy
4. Biopsy of organs with risk.

Furthermore, it should be remembered that there are certain procedures in which the specific legislation that regulates them already includes the need to secure IC, whereby centres drawing up lists must therefore include them. These procedures are:

1. Donation and reception of blood-derived products
2. Extraction and transplant of organs and tissues
3. Necropsies
4. Clinical trials
5. Assisted human reproduction techniques
6. Abortion.

CONSENT FOR MEDICAL-SURGICAL PROCEDURES

SURNAME(S) AND NAME.....

AGE **NO. HC**

Description of the procedures proposed and their consequences

Cholecystectomy (by open or laparoscopic route) is the removal of the gallbladder. This requirement is due to the fact that the person is a carrier of lithiasis or gallstones that provoke colic, infections or episodes of pancreatitis. It is performed with general anaesthetic and a radiography with contrast is often performed during surgery. The lack of a gallbladder has no consequences: the patient can eat without any restrictions and lead a normal life.

Proposing service...General surgery.....

Indicating and reporting doctor ...Dr......

Service performing it *General surgery and anaesthesiology*

I have been properly and sufficiently informed on the need for these procedures and **the alternatives**: not operating would mean that the danger involved in the aforementioned problems would persist. In the **open route** (classic) the incision will be, in most cases, subcostal (below the ribs, right side) or in the midline of the abdomen. In the **laparoscopic route** three or four minor incisions are made between the navel and the abdomen, and the post-operative period is theoretically shorter. The choice must be made by the doctor, according to many parameters, and sometimes the laparoscopy will become open if there are technical difficulties.

General risks

Any procedure entails certain risks: infection, haemorrhage (and other more serious, but less frequent ones, such as cardiorespiratory arrest). **This procedure**, furthermore, also includes bile leak and residual calculus. Drainage, which is subsequently withdrawn, is often placed to control bleeding or bile leak. A radiography will be performed to view the bile duct in order to prevent residual calculus; if there are any doubts as to the presence of gallstones they may need to be removed with a more complicated operation by opening the intestine, or else later by endoscopy. As also occurs in any operation, weak areas may be left in the wound in the abdomen (eventrations), that sometimes require correction with a further operation.

I have also been informed as to the **personal risks**, in my specific case:

.....

as well as the possible need for **the modification of the scheduled operation** with a view to solving my problem of

Any doubts I had were cleared up after listening to and reading the specific information I was given. I also know that I can reject the procedure and that I can always go back on any decision I take now.

To all the foregoing, I freely (DO OR DO NOT) GIVE MY CONSENT.

I agree to have the procedures indicated carried out by the services in question, with the limitation of

.....

PLACE AND DATE....., 200.....

SIGNATURE :	Patient	Informing doctor	Legal representative	Witness
	Mr./Ms.....	Dr.....	Mr./Ms.....	Mr./Ms.....

CONSENT FOR MEDICAL-SURGICAL PROCEDURES

Surnames and name.....

Age..... **No. HC**.....

Description of the procedures proposed.....

.....
.....
.....

Services proposing them.....

Informing doctor Dr.....

Services that will perform it/them.....

I have been given sufficient information on the certain or very probable consequences of the procedure:

.....
.....

on its **general risks**. Any procedure entails certain risks, such as infection, haemorrhage (and other more serious, but less frequent ones, such as cardiorespiratory arrest). In this procedure, mention must be made of :.....

.....
.....
.....
.....

I have also been informed of the **personal risks** in my case:

.....
.....
.....
.....

as well as of the possible need to **modify the scheduled operation** to solve my problem of.....

.....

Any subsequent doubts I had were also dispelled on receiving the oral information, and that which is contained in the (mark with an X) book....., video, or which is attached to this sheet.

I also know that I can reject the procedure and that I can always go back on any decision I take now.

IN VIEW OF THE FOREGOING I FREELY (DO or DO NOT) GIVE MY COMNSENT for the procedures indicated, with the exception of
.....

Place and date,of.....200.....

Signature of the patient Reporting doctor Legal representative, if necessary

CONSENT SHEET FOR THE STUDY OF THE GENETIC BASES IN ALZHEIMER'S DISEASE AND OTHER DEMENTIAS

READ the following information to make sure that you understand perfectly the objective of this donation and the study that will be performed, and sign it if you agree to make a donation or participate in the study:

To summarise, this project aims to ascertain the possible genetic bases that may impact the development of any type of cognitive deterioration and behaviour and more particularly Alzheimer's disease, vascular dementia or other types of dementia.

PROCEDURES to carry out this study

Blood samples will be required, which will be used to obtain the genetic material, which will be used for different analyses.

BENEFITS

You will receive no direct benefits for participating in the study, since the results will be of scientific interest. Nevertheless, you will be informed if the data could afford you a potential benefit with regard to your disease, unless you have already stated in writing that you do not wish to receive this type of information.

EXPENSES

All expenses will be fully met by the parties involved in the study, and as a blood donor you have no responsibility whatsoever in this regard.

CONFIDENTIALITY

Confidentiality is guaranteed, which means that all data is always kept anonymous. The results of the study will therefore be stored in specific archives created specifically for this end and will be protected with the safety measures required by the legislation in force. These data are not included in your clinical history.

The results obtained may be consulted by the investigators of the study and be published in scientific journals without the personal data of the donors being mentioned.

You may request access to your personal data at any time if you wish to change them; as well as withdraw this authorisation. To do so you must write to (study investigator/s). Your request will be attended to immediately and the latest blood samples you provided will be destroyed.

The signature of this consent sheet makes it possible to use the blood samples in this research study.

CONSENT

Having read and understood the objective of the study, and after any doubts I had have been cleared up, I agree to participate in it.

PLACE and DATE,..... of 200.....

SIGNATURE: Patient Reporting doctor Legal Representative Witness
(if necessary)

Mr./Ms.....

Dr.....

Mr./Ms.....

Sr./Ms

**INFORMED CONSENT SHEET FOR THE CONDUCT OF A DIGESTIVE
ENDOSCOPY**

Mr./Ms.....

I give my consent to undergo an endoscopy, whose nature and finality has been explained to me by Dr..... I have understood the information given to me and the clarifications I asked for on the procedure. I also give my consent if any biopsies, photographs of the parts which are the object of the endoscopy or radiological explorations need to be performed.

Warnings

1. For the conduct of the gastroscopy, dilatation and insertion of a stent into the oesophagus, placement of a PEG probe or other endoscopic procedure

I have understood that all types of endoscopy entail a small risk of haemorrhage or perforation which would have to be repaired surgically. There are other rare complications, which include aspiration pneumonia and a reaction to the i.v. sedative medication given to relax me. In the upper part, the endoscopy may involve teeth or denture (prosthesis) problems.

2. To perform a colonoscopy and a flexible sigmoidoscopy

I have understood that these tests entail a small risk of lesion in the large intestine which would have to be repaired surgically. The risk of perforation or bleeding is greater if polyps have to be removed from me by biopsy or by polypectomy.

2. For the placement of probes for retrograde cholangiographies

I understand that ERCP is an endoscopic procedure that may damage the bile duct or produce cholangitis (infection of the bile duct) or a pancreas inflammation. In the event of anal fissure rendering endoscopy necessary, the latter increases the risk of haemorrhage or perforation. If a stent is inserted into the bile or pancreatic duct to unblock them and reduce jaundice, this occasionally leads to cholangitis or pancreatitis. I also understand that the stent may have to be changed occasionally.

***Score out the part that is not applicable**

.

PLACE and DATE,..... of 200.....

SIGNATURE: Patient

Mr./Ms.....

I confirm that I have explained the nature and the objective of endoscopic procedure to the patient, Mr./Ms.....

Reporting doctor

Dr.....

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