Quick guide

Confection of informed consent

Summary of important aspects from the *Guide of Recommendations on Informed Consent* of the Bioethics Committee of Catalonia.

N8590 | Document Management Unit

1. Definition

Informed consent is the free, voluntary and conscious agreement of a patient, expressed in the full use of his or her faculties after receiving the appropriate information, for an action that affects his or her health to take place. - GENCAT[1]

2. Legal references

Informed consent in Catalonia is regulated by **Law 21/2000, of 29 December, on the rights to information concerning health and patient autonomy, and clinical documentation** (articles 6 and 7 of chapter IV).

In Spain, there is Law 41/2002, of 14 November, basic regulation of patient autonomy and rights and obligations in matters of information and clinical documentation (articles 8, 9 and 10 of chapter IV)

3. Ethical aspects

- Clinical information must be adapted to the needs of each patient, bearing in mind that they may vary from one patient to another and from one moment to another.

No document read and signed can ever be a substitute for dialogue.

- The quantity, form and pace of the information and even the requirements for the signing of documents must be appropriate to the needs of each patient and, therefore, a flexible framework for action is needed.
- In cases of substitution of the will of the person affected, the decision must be as objective and proportional as possible in favour of the patient and with respect for their personal dignity. Likewise, the patient must be involved as much as possible in the decision making process.

4. General recommendations for the drafting of the IC

- Written information should be as personalised and intelligible as possible, but avoiding the defensive use of documents.
- The information must be appropriate to the needs of the patient and the procedures, defying unnecessary exhaustiveness.
- We must prevent the secrecy of medical terms from undermining true communication. In this sense, clarity is better than exhaustiveness.
- At this point, patients should be encouraged to understand the opportunity and the overall risk of what is being offered to allow them to become involved in the decision. The ideal is that the information should be essentially open to them:
  - Advances of the intervention.
  - Certain or very probable consequences.
  - Typical risks inherent to the procedure.
  - Custom Risks

[1] https://seguretatdelspacients.gencat.cat/ca/detalls/article/Consentiment_informat

- Although it is foreseeable that in the future there will be more patients who will want full information, it is important to take into account and respect those who do not wish to receive it.
- The documents must include minimum information sections (mentioned in the following chapter of this Guide) that must be adequately filled in for each situation.
- In all cases in which the patient has expressed their informed consent in writing, they will have the right to be given a copy of the signed document.
- The information prior to consent must be given sufficiently in advance and within the appropriate framework to allow for calm reflection and, if necessary, to revoke this consent.
- The open and basic document, which can be common to many procedures, **can never end up being generic, but must specify the proposed procedure and its specificities**.

5. Structure of the contents and specific recommendations for the preparation of the IC

Our hospital's template for the preparation of informed consents is made up of 7 main sections:

1. **Name of the procedure**	Name of the medical or medical-surgical procedure to be performed.
2. **Objective**	Objectives pursued.
3. **Description of the procedure**.	What it consists of. Explanation of the procedure/s proposed and the benefits expected from the medical procedure.
4. **Consequences than They always happen.**	Description of the consequences for the patient (e.g. colostomy, in some cases scarring).
5. **General risks**.	Typical risks or those inherent to the procedure. All those that occur very frequently or which, although rare, are very important. This type of information is the most discussed and is where the concept of adequate information established by the Council of Europe Convention must be applied the most. On some occasions, extensive and in-depth information may be required, either by the patient's own will or because the low benefit and high risk make it advisable. On other occasions - for example, due to delegation or verbal renunciation by the patient, manifest anguish or urgency - and if the indication is clear, the information may not be exhaustive, but it must be sufficient, intelligent and loyal to the patient.
6. **Personalised risks**	This space is reserved for specifying (if necessary) personalised risks due to the problems of the specific patient, their previous pathology, or serious risks taking into account their profession or life expectancy.
7. **Alternatives**.	Treatment alternatives and their effectiveness and safety compared to the proposed procedure.
8. Procedure codes	It is necessary to indicate to which service code(s) the IC will be linked. If the service does not know it, we have the support of the Coding Unit.

But there are other sections that the system that generates the IC from SAP automatically adds:

1. **Identification of the patient or responsible person. Include:** Name and surname(s); DNI and Relationship with the patient (when it is the patient's responsible person)	In the case of a minor or a person incapable of giving consent, the responsible person is identified.
2. Last name and name of the doctor / the doctor which reports	It includes the identification of the service from which the information is provided.
3. Register number	
4. Legal text of the Authorisation	Declaration by the patient of having satisfactorily received the information and of having been able to raise any doubts they may have.
5. Space for signatures	Patient and professional
6. Date of signatures	
7. Legal text of the Revocation:	Information on the right to accept or reject what is proposed and to withdraw from consent now decided; and information on the right toExplicitly state the limits that you consider appropriate (for example, that you do not want blood transfusion or total mastectomy).
8. Signature and date of revocation	