

NATIONAL ETHICS COMMITTEE FOR CLINICAL TRIALS

ANNEX TO THE CIRCULAR OF 01.10.2026

Detailed guidance on the informed consent documents addressed to subjects

This is a translation of the Greek text. In case of divergence, the Greek version prevails.

1. Purpose and scope of the annex

This annex is issued pursuant to chapter 5 of the Circular of 01.10.2026 and provides detailed guidance on the content, structure and language of the informed consent documents addressed to subjects.

The substantive requirements are laid down in the Circular and procedural matters in the Questions and Answers document. This annex does not reproduce their content and refers to them; in case of conflict, the Circular prevails.

It applies to clinical trials with medicinal products under Regulation (EU) No 536/2014, to clinical investigations of medical devices under Regulation (EU) 2017/745 and to performance studies of in vitro diagnostic medical devices under Regulation (EU) 2017/746. Chapters 2 to 4 are common, while the specific adaptations for medical devices and in vitro diagnostic medical devices are set out in chapter 5.

2. Informed consent document

2.1 Content of the informed consent document

The content of the document is drawn up in accordance with the harmonised Union template. This annex neither replaces nor reproduces that template, but provides the national specifications and the guidance on language and style that apply in addition. The sponsor completes the template and then checks the Greek text against chapters 2.2 to 2.5 below.

As regards terminology, chapter 2 of the Circular applies.

2.2 Structure and readability of the informed consent document

The information text and the consent page constitute a single document; as regards identification and pagination, chapter 4 of the Circular applies.

The document must be complete and clear, and also concise. Excessively long texts undermine reading and understanding before signature. Information is not repeated, is not self-contradictory and is consistent with the protocol. Details may be given in an annex, without an excessive number of annexes. The structure must allow the reader to find easily the points of interest. The font size must be legible.

2.3 Language and style of the informed consent document

As regards the language of the documents and responsibility for the rendering, chapter 3 of the Circular applies. In addition:

The language must be simple and understandable by the average prospective subject. Specialised and foreign-language terms are avoided. Abbreviations are avoided; where they are necessary, the term is written out in full the first time, with the abbreviation in brackets.

Expressions that may cause fear, confusion or unfortunate associations are not translated word for word. Randomisation, for example, is rendered as random allocation by an automated system, and not through similes suggesting risk-taking or games of chance. As regards blood volumes, stating the figure in ml is sufficient, possibly with a comparison to a corresponding routine procedure. Volumes taken from paediatric subjects are consistent with the limits of the relevant guidelines or of established clinical practice.

The language is courteous and sensitive, taking into account the particular features of the study population. Expressions that offend the subject or place the subject in a disadvantageous position are avoided.

2.4 Adaptation to Greek circumstances

Epidemiological data do not relate to third countries alone, but at least to European or global data. The same applies to the availability of a marketing authorisation or CE marking, to trade names and to public registers. The competent bodies are correctly identified, without confusion between the National Organisation for Medicines and the Committee.

The characteristics of the subjects are taken into account and general information is not given impersonally by copying standardised texts. A document addressed to the parents of infants or toddlers does not include information on the risks of pregnancy or breastfeeding.

The document is common to all trial sites, with site-specific details alone varying; those details are described in exactly the same way in all submitted documents. The blanks provided for each site may, following the Committee's opinion, be completed and supplied pre-printed, so as to avoid omissions.

2.5 Guidance by section of the informed consent document

2.5.1 Description of the study

In a randomised study it is made clear that the subject may not receive the investigational product, that the subject may receive a placebo, and what the corresponding probabilities are. The alternative treatments outside the study and the treatment after its completion are stated.

The procedures are described in full, together with their purpose and any risks or discomfort, in an understandable manner: the risks of radiation, for example, are presented by reference to a more common procedure with which the average patient is already familiar. They are not described visit by visit; instead, the study flow chart may be included as an annex.

In an interventional study it is not acceptable to allow it to be understood that the subject will derive direct personal benefit.

2.5.2 Adverse reactions

The term "adverse reactions" is used rather than "side effects". All of them are stated, consistently with the Investigator's Brochure or the document replacing it or, as the case may be, with the current Summary of Product Characteristics, under the responsibility of the sponsor. For terms that are difficult to understand, a plain-language explanation is also given. Where a Greek Summary of Product Characteristics is available, the most serious adverse reactions may be stated and the current version supplied as an annex. The adverse reactions or discomfort arising from the procedures themselves are also stated.

2.5.3 Pregnancy, breastfeeding and contraception

Specific and detailed information is given on the risks of the investigational product and on the avoidance of pregnancy, and all acceptable and unacceptable methods of contraception are stated, together with any other restrictions, such as the donation or storage of oocytes or sperm. Where an additional specific document on pregnancy exists, it is referred to in the main document, with its version and date. The pregnancy clause of the insurance cover is not repeated in the consent document.

Given that the possibility of an unforeseen pregnancy remains real even under strict contraceptive measures, international guidance requires the systematic follow-up and recording of the outcome of every direct or indirect exposure to an investigational product, in order to detect signals of embryotoxicity or congenital anomalies. Accordingly, submitting in advance an informed consent document for pregnancy follow-up (Pregnancy ICF) ensures operational readiness and the immediate start of lawful follow-up of the event.

2.5.4 Restrictions during the study

The contraindications and precautions provided for in the protocol are stated as regards medicinal products, food supplements and foods, including live vaccines, over-the-counter preparations and herbal preparations. In the case of herbs in particular, their common names are also stated, so as to avoid errors. Restrictions on the consumption of alcohol and on smoking are also stated, as is the avoidance or limitation of activities.

2.5.5 Costs and financial benefits

The informed consent document includes the statement provided for in chapter 5 of the Circular, namely that the investigational and auxiliary products, the procedures required by the protocol and the management of any adverse reactions are provided free of charge, at no cost to the subject, the hospital or the subject's insurance body.

Every benefit envisaged for the subject is described as to its nature, amount and method of payment, consistently with what has been declared in the dossier. As to which benefits are permissible, the Questions and Answers document applies.

2.5.6 Biological samples and genetic analysis

The informed consent document informs the subject of the collection, storage and any future use of biological samples. Where the possibility of further or genetic analysis is envisaged, this is expressly stated and a field is provided so that the subject may express a view on whether he or she wishes to know or not to know the findings.

For procedures that are not mandatory for participation, a separate document is required, containing self-standing information on that procedure alone, without repeating the information in the main document, to which reference is made.

2.5.7 Contact in the event of withdrawal

The informed consent document provides for the possibility for the subject to designate, in writing and separately, relatives or other persons whom the investigator may contact should the subject withdraw. The designation is recorded in the signed document. Consent to the use of a patient location service is given in a separate document, which states expressly that a refusal does not preclude participation.

2.5.8 Protection of personal data

This section is drafted under Regulation (EU) 2016/679 and Law 4624/2019. Every reference to the repealed Law 2472/1997 and every reference to an obligation to notify files to the Hellenic Data Protection Authority cease to apply. The document states as a minimum:

- the identity and contact details of the controller and of the data protection officer,
- the purposes and the legal basis of the processing,
- the categories of data and their recipients,
- the retention period,
- the rights of the data subject, how they are exercised and their restrictions in the context of scientific research,
- the right to lodge a complaint with the Hellenic Data Protection Authority.

Where transfer of data to a third country without Union safeguards is envisaged, express information to that effect is included, naming the country, in accordance with chapter 8 of the Circular.

Data entered in the study database under a code number are pseudonymised and not anonymous, where authorised personnel are able to link them to the identity of the subject. The term "anonymous" is not used for such data. Indicative wording:

"On entering the study you are given a code number. Your data are recorded under that code and not under your name. Only the authorised study personnel can link the code to your identity. Your data are therefore not anonymous but pseudonymised, and they continue to be protected as personal data."

Scientific conclusions, communications and publications are presented in aggregate form and do not disclose the identity of the subject. For clinical trials with medicinal products, the reference to public registers is to the public workspace of CTIS; reference to other registers is made only where the study is in fact registered in them.

For quality assurance purposes, the sponsor or its authorised representatives and the authorised representatives of the competent authorities must review the subject's medical records. The information remains confidential and no copies are taken of documents disclosing the subject's identity.

2.5.9 Summary list

It is recommended that a summary of the main points be set out at the end of the information text, namely that sufficient time was given and questions were answered, that participation is free and may be withdrawn without consequences for future care, that the subject will receive a signed copy, that the subject bears no financial burden, and that the subject has been informed about the insurance cover, about the methods of contraception where applicable, about access to his or her medical records and about the protection of his or her data.

2.5.10 Consent page

The signature fields and the situations in which impartial witnesses are present are laid down in chapter 5 of the Circular and are not repeated here.

As regards format, tick boxes scattered throughout the text are avoided and all questions are brought together in one place, with a separate dated signature of the subject and of the member of the research team for each of them. Ticking a box or writing initials does not replace a signature.

3. Specific informed consent documents

3.1 Minors

Who gives consent and under what conditions is laid down in the Circular and in the Questions and Answers document. This annex concerns the form and content of the information material.

The material is adapted to the age and to the cognitive and developmental level of the minor, separate from the documents of the parents or legal representatives and differentiated by age group. The parents receive the full information, while minors receive as much as is consistent with their age and their obligations, without financial information.

On account of differing intellectual and social maturity, the documents are differentiated by age range: 10 to 12, 13 to 15 and 16 to 18 years. Depending on the effect of the investigational product on pregnancy or on the foetus, the information on contraception is full for those over 16, more general for those aged 13 to 15 and summary for those aged 10 to 12. Adolescents receive full information on the restrictions regarding the use of medicinal products and other substances, the consumption of alcohol, smoking and activities.

For children who do not give written consent, an information document is prepared, adapted to the age range and, where appropriate, illustrated. The information is given by investigators or team members trained or experienced in working with children.

3.2 Persons lacking or with limited legal capacity

Information material is prepared that is adapted to the degree to which the subject is able to understand, separate from the document of the judicial assistant. The subject's own document states in simple terms that his or her wish to refuse or to withdraw is binding.

3.3 Carer

Where, on account of the nature of the condition, there is a carer, information is also provided to that person, so as to ensure that the procedures and instructions are followed. The information is assessed case by case and is generally similar to that given to the subject. In specific cases it also includes information concerning the carer personally, as to the precautions to be taken during administration and the measures to be taken in the event of accidental exposure to the investigational product.

3.4 Pregnant partner

The above apply where relevant. Given that this person has not been selected as a subject, and that it is not possible to foresee her capacity to consent or to sign, the signature page always provides fields for witnesses as well.

3.5 Documents in another language

Where the enrolment of subjects who do not adequately understand Greek is envisaged, a translation of the approved Greek documents into the subject's language is submitted, the approved Greek version always serving as the source text.

4. Amendments to the documents

Amendments concerning the safety of subjects are incorporated as soon as possible after the date of the corresponding international version. With every amendment, the revised version is submitted in clean form and with the changes marked against the previous version. The version number and the date are updated on all pages.

5. Medical devices and in vitro diagnostic medical devices

Chapters 2 to 4 also apply to clinical investigations of medical devices and to performance studies, with the following adaptations.

The terms "clinical investigation" and "performance study" are used instead of the term "clinical trial", and the header or footer states the CIV identifier of the investigation under the relevant Regulation instead of the EU CT number.

Information and consent are governed by Article 63 of Regulation (EU) 2017/745 and, respectively, by Article 59 of Regulation (EU) 2017/746. The content is adapted to the nature of the product: the procedures for placement, use or removal are described, as are the duration for which the device remains in place, the risks connected with the product itself rather than with pharmacological action, and what becomes of the product after the end of the investigation.

In performance studies it is clearly described whether and how the results of the test will be communicated to the subject or to his or her treating physician, and whether they will be used in taking clinical decisions.

As regards insurance cover, Article 69 of Regulation (EU) 2017/745 and Article 38 of Law 4931/2022 apply in addition. The method of submission is described in the Questions and Answers document.