

HELLENIC REPUBLIC
MINISTRY OF HEALTH
NATIONAL ETHICS COMMITTEE FOR CLINICAL TRIALS of GREECE

CIRCULAR

1 October 2026

SUBJECT: Clarifications of the National Ethics Committee for Clinical Trials on matters within its remit

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

1. Purpose, scope and relationship with the Questions and Answers document

This circular is issued in replacement of the circular of 11.10.2019 and sets out the substantive requirements of the Committee, in particular as regards the documents addressed to subjects. The method of submission, the correspondence of documents with the sections of the dossier and procedural matters are described in the Committee's Questions and Answers document, which is updated more frequently and refers back to this circular.

This circular applies, as regards Part II of the application, to clinical trials with medicinal products under Regulation (EU) No 536/2014, as well as 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.

Applications for clinical trials with medicinal products are submitted electronically through the Clinical Trials Information System (CTIS) only. Applications for clinical investigations of medical devices and for performance studies are submitted electronically, to the registry e-mail address of the National Organisation for Medicines (protokollo@eof.gr), for the attention of the Committee. Once the relevant application system becomes operational, the method of submission will be notified by a relevant announcement.

The Committee's announcements remain in force and supplement this circular. An index of them, with dates and links, is included in the Questions and Answers document. Where their content is to the contrary, the later text of the circular prevails.

2. Terminology

Where this circular refers to the "investigational product", this means, as the case may be, the investigational medicinal product, the investigational medical device or the in vitro diagnostic medical device that is the subject of the performance study.

The term "informed consent" is rendered in Greek as "συναίνεση κατόπιν ενημέρωσης". Consent constitutes a declaration of permissive will, that is, prior agreement and acceptance by the person concerned after having been fully informed. The Greek term "συγκατάθεση" has a broader meaning, as it also covers subsequent approval of something that has already taken place, and is therefore not apt in the context of clinical studies.

3. Language and responsibility for the rendering

The Committee gives its opinion on the Greek version of the documents addressed to subjects, which is the only valid version for Greek trial sites. The accuracy of the rendering from the corresponding foreign-language version is the sole responsibility of the sponsor, who must take into account Greek legislation and the guidance of the authorities.

Where the enrolment of subjects who do not adequately understand Greek is envisaged, a translation of the approved Greek consent documents into the subject's language is submitted.

4. Identification of documents

Every document is identified in the header or footer, on every page, by the type of document, the protocol code or study acronym, the version number and the date, together with the EU CT number or, as the case may be, the EUDAMED CIV ID. Pagination is continuous and shows the total number of pages.

The study title is stated in identical wording across all documents, and the trial sites and Principal Investigators are described in exactly the same way throughout.

5. Informed Consent Document

The content of the informed consent document is drawn up in accordance with the harmonised Union template. In addition, that document must include the following:

- a statement 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, in accordance with Article 15 of Ministerial Decision Government Gazette B' 4131. Any term to the contrary is deemed unwritten,
- specific and detailed information on the risks of the investigational product and on the avoidance of pregnancy, where this is material given the nature of the study,
- information on the collection, storage and any future use of biological samples, as well as on the subject's right to know or not to know the findings of genetic analysis, with the subject's view expressly recorded,
- information on the possibility for the subject to designate, in writing and separately, relatives or other persons whom the investigator may contact should the subject withdraw,
- where transfer of data to a third country without Union safeguards is envisaged, express information to that effect naming the country, in accordance with chapter 8,
- contact details of the research team,
- name and signature fields as set out below, according to the population provided for in the protocol:
 - in every case, a field for the subject and a field for the member of the research team who conducted the interview,
 - for minors, a field for the minor and two fields for the parents jointly exercising parental care or, where the minor is under guardianship, a field for the guardian,
 - for persons lacking or with limited legal capacity, a field for that person and a field for the definitive judicial assistant,
 - where enrolment in emergency situations is envisaged, a field for the legally designated representative under Article 12 of the Ministerial Decision,
 - name and signature fields for witnesses, as set out below.

Amendments concerning the safety of subjects are incorporated into the documents as soon as possible after the date of the corresponding international version.

The title "Έντυπο Συναίνεσης μετά από Ενημέρωση" (Informed Consent Document) is stated in the title of the document and in the header or footer. The subject card is submitted in Greek as a document addressed to the subject.

Impartial witnesses: Under Article 9 of Ministerial Decision G5a/59676/22.12.2016 (Government Gazette B' 4131), the witness must have legal capacity and must not be connected in any way with the clinical trial. Where the subject is deaf or unable to speak, at least one witness is present throughout the process and co-signs the information document and the consent document. Where the subject is unable to write or to read, the documents are signed by the designated member of the research team and by two witnesses. Where consent is recorded through appropriate alternative means, at least one witness is present and co-signs.

In the ordinary case no witness is required: The Committee recommends that name and signature fields for witnesses be provided in the document as a precaution, so that a fresh submission is not needed should

one of the above situations arise. Where the protocol excludes subjects who cannot sign for themselves, no fields for a legally designated representative or for witnesses are provided.

Minors: Information material is prepared that is appropriate to the age and developmental level of the minor, separate and self-standing in relation to the documents of the parents or legal representatives and differentiated by age group. As soon as the minor acquires the legal capacity to consent, a separate information and consent document is provided.

Persons lacking or with limited legal capacity: Under Article 10 of the same Ministerial Decision, the written consent of the person is obtained where and to the extent that he or she is able to understand, and an express wish to refuse or to withdraw is binding. The written consent of the definitive judicial assistant is also required, which expresses the presumed will of the subject and may be freely withdrawn.

Emergency situations: Enrolment takes place under Article 35 of Regulation (EU) No 536/2014. Under Article 12 of the Ministerial Decision, and for the purposes of that Article only, the legally designated representative also includes the spouse, the partner under a cohabitation agreement, the adult descendants or ascendants of the patient and the patient's siblings, from whichever of them informed consent can be obtained soonest.

Detailed guidance on the informed consent document is set out in the annex to this circular.

6. Information for the recruitment of subjects

The term "advertising" is avoided as inapt, since it suggests financial gain and a commercial transaction, which do not correspond to the environment of clinical studies. The correct term is "information for the recruitment of subjects". The following apply:

- Only non-interactive information is permitted, such as printed or electronic leaflets, audio messages, posters and placements in the mass media.
- Placement on social media is not permitted.
- Links and QR codes pointing to websites are not accepted, because website content can change without any possibility of tracking those changes.
- Interactive information is not permitted, such as online platforms involving the entry of personal data of the prospective subject, nor the collection of sensitive personal data through an electronic or telephone questionnaire by an information company.
- The content of the information, the websites that will host it and the means and places of distribution of the material are submitted to the Committee for its opinion. The same applies to any material addressed to physicians so that they may refer subjects to the trial sites.

Beyond repeating the inclusion and exclusion criteria of the protocol, the means of approaching and selecting prospective subjects are described, together with any particular features of the protocol, such as the participation of vulnerable populations.

7. Documents or benefits for subjects

Every document or benefit intended for subjects, their relatives or carers is submitted for the Committee's opinion.

The benefit is justified by reference to the needs of the study, and its value must be reasonable, so that it does not operate as an inducement to participate.

As to which financial benefits to subjects are permissible, the Committee's announcement of 22.07.2026 applies.

8. Transfer of personal data to third countries

A request for transfer is submitted together with an official statement by the sponsor or an authorised representative, stating the number of the contract with the recipient of the data in the third country and that the contract ensures compliance with the safeguards provided for by Regulation (EU) 2016/679.

Where no such contract exists, the applicant states the reason and may provide for specific consent of the subject to the transfer, on condition that the informed consent document contains express information that the safeguards of the Union do not apply in the third country, which is named.

Names, contact details and curricula vitae of persons representing the sponsor, such as trial monitors, are not submitted to the Committee, in application of the data minimisation principle. Contact details continue to be stated in the application and in the cover letter.

9. Pregnancy clause in the insurance cover

In addition to the requirements of Article 15 of Ministerial Decision G5a/59676/22.12.2016 (Government Gazette B' 4131), the insurance certificate includes, in the event of pregnancy of a participant or of the partner of a participant and where this is material given the nature of the study, an express reference to cover of the neonate for harm to its health attributable to the study, in the following wording:

"In the event that the participant, or the partner of a participant, becomes pregnant despite the specific and detailed information provided in the protocol and in the informed consent document concerning the risks of the investigational product and the avoidance of pregnancy, and where termination of the pregnancy is not possible for medical or conscientious reasons, if the neonate presents health problems that are attributable to the investigational product or to the procedures required by the protocol, the neonate is covered and insured."

The Greek wording of the clause is set out in the Greek version of this circular.

For clinical investigations of medical devices and for performance studies, Article 69 of Regulation (EU) 2017/745 and Article 38 of Law 4931/2022 apply in addition.

10. Consequences of non-compliance

Non-compliance with the above is identified during the assessment and leads to a request for information (RFI) addressed to the sponsor or, as the case may be, to a negative opinion or an opinion subject to conditions.

11. Repeals

From the issue of this circular, the Committee's circular of 11.10.2019 and any other earlier circular or announcement to the contrary are repealed.

The Chair of the National Ethics Committee for Clinical Trials

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