Guideline
7.5.2026
T/448/2026

The documents mentioned in the Annex I of the EU Clinical Trials Regulation (536/2014) and other relevant documents regarding the assessment of Part II of the application dossier

Unless otherwise stated, the documents can be submitted in English. A signature is not required in the documents. Please submit the documents in a PDF or PDF/A form.

This guideline presents sections K–R (points 59–73) of Annex I of the Clinical Trials Regulation, as well as the national requirements and remarks.

K. RECRUITMENT ARRANGEMENTS

59. Unless described in the protocol, a separate document shall describe in detail the procedures for inclusion of subjects and shall provide a clear indication of what the first act of recruitment is.

National requirements and remarks:

The published template *Recruitment and Informed consent procedure* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en.

The template can be used for the description referred to in section K, point 59. In addition, the requirements set out in sections 13–15 of the Act on Clinical Trials on Medicinal Products (983/2021) must be followed where applicable.

60. Where the recruitment of subjects is done through advertisement, copies of the advertising material shall be submitted, including any printed materials, and audio or visual recordings. The procedures proposed for handling responses to the advertisement shall be outlined. This includes copies of communications used to invite subjects to participate in the clinical trial and arrangements for information or advice to the respondents found not to be suitable for inclusion in the clinical trial.

National requirements and remarks:

The documents shall be written in Finnish and/or Swedish. Videos or audio recordings are not to be submitted with the application. However, a transcript must be included for audio recordings, and a transcript or a storyboard for videos. The ethics committee may request additional information if necessary.

L. SUBJECT INFORMATION, INFORMED CONSENT FORM AND INFORMED CONSENT PROCEDURE

National requirements and remarks:

The published template *Recruitment and Informed consent procedure* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en.

When using mentioned template for Annex I, section L, it shall be fulfilled in Finnish and/or Swedish.

61. All information given to the subjects (or, where applicable, to their legally designated representatives) before their decision to participate or abstain from participation shall be submitted together with the form for written informed consent, or other alternative means according to Article 29(1) for recording informed consent.

National requirements and remarks:

Tukija has published an *Information Sheet and Consent Form template* on its website: https://tukija.fi/en/applications-under-regulation. The participant information sheet and informed consent form shall be written in Finnish and/or Swedish.

The Swedish version of the participant information sheet does not need to be submitted to the CTIS after the Finnish version has been approved.

For participants who do not speak Finnish or Swedish, all patient facing documents must be provided in a language they understand. In addition to the translation of the participant information sheet and informed consent form, the use of an interpreter throughout the research is necessary, provided that the research team does not speak the language in question. This enables the safe conduct of the trial and allows participants to ask questions or withdraw from the study at any time. The interpreter must be familiar with clinical trials, with the culture of the person in question, and with the Finnish operating environment.

The material of this section must include the information required under Articles 12–14 of the EU General Data Protection Regulation (2016/679). It can be for example a separate document or an annex to the participant information sheet.

62. A description of procedures relating to informed consent for all subjects, and in particular:

(a) in clinical trials with minors or incapacitated subjects, the procedures to obtain informed consent from the legally designated representatives, and the involvement of the minor or incapacitated subject shall be described;

(b) if a procedure with consent witnessed by an impartial witness is to be used, relevant information on the reason for using an impartial witness, on the selection of the

impartial witness and on the procedure for obtaining informed consent shall be provided;

(c) in the case of clinical trials in emergency situations as referred to in Article 35, the procedure for obtaining the informed consent of the subject or the legally designated representative to continue the clinical trial shall be described;

(d) in the case of clinical trials in emergency situations as referred to in Article 35, the description of the procedures followed to identify the urgency of the situation and to document it;

(e) in the case of clinical trials where their methodology requires that groups of subjects rather than individual subjects are allocated to receive different investigational medicinal products, as referred to in Article 30, and where, as a consequence, simplified means for obtaining informed consent will be used, the simplified means shall be described.

National requirements and remarks:

The documents shall be written in Finnish and/or in Swedish. Article 30 of the Clinical Trials Regulation is not applicable in Finland.

63. In the cases set out in paragraph 62, the information given to the subject and to his or her legally designated representative shall be submitted.

National requirements and remarks:

The document shall be written in Finnish and/or in Swedish.

M. SUITABILITY OF THE INVESTIGATOR

64. A list of the planned clinical trial sites, the name and position of the principal investigators and the planned number of subjects at the sites shall be submitted.

National requirements and remarks: No remarks.

65. Description of the qualification of the investigators in a current curriculum vitae and other relevant documents shall be submitted. Any previous training in the principles of good clinical practice or experience obtained from work with clinical trials and patient care shall be described.

National requirements and remarks:

The published template *Investigator Curriculum Vitae* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en.

66. Any conditions, such as economic interests and institutional affiliations, that might influence the impartiality of the investigators shall be presented.

National requirements and remarks:

The published template *Declaration of Interest* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en.

N. SUITABILITY OF THE FACILITIES

67. A duly justified written statement on the suitability of the clinical trial sites adapted to the nature and use of the investigational medicinal product and including a description of the suitability of facilities, equipment, human resources and description of expertise, issued by the head of the clinic/institution at the clinical trial site or by some other responsible person, according to the system in the Member State concerned, shall be submitted.

National requirements and remarks:

The published template *Site Suitability Template* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en.

A statement of the suitability of the facilities may be submitted either separately for each clinical trial site, or in a single document where the sites are clearly separated.

The statement can also be done by the contact person of the sponsor or someone else who is representing the sponsor.

O. PROOF OF INSURANCE COVER OR INDEMNIFICATION

68. Proof of insurance, a guarantee, or a similar arrangement shall be submitted, if applicable.

National requirements and remarks:

Section 5 of the Act on Clinical Trials on Medicinal Products: “The sponsor shall ensure that insurance or other appropriate guarantee to compensate for damage suffered by participants is in place that covers the sponsor's and investigator's liability”.

A separate description of the insurance or other appropriate guarantee shall be submitted.

P. FINANCIAL AND OTHER ARRANGEMENTS

69. A brief description of the financing of the clinical trial.

National requirements and remarks:

Part II of the application shall be accompanied by an explanation of the basis for determining the compensations to be paid to investigators and other clinical trial personnel, its amount, and its reasonableness.

The information shall include:

- Sponsor of the clinical trial.
- Any conflicts of interest and/or commitments of investigators and/or other clinical trial personnel related to the sponsor of the clinical trial.
- The total costs of the trial site/sites and the basis for their formation (administration, premises, equipment, laboratory, and other services).
- Investigators' fees, estimated in euros (can be reported either as subject-specific or visit-specific fees).
- Remunerations of other clinical trial personnel, estimated in euros (can be reported either as subject-specific or visit-specific fees).
- Resources related to recruiting subjects.

70. Information on financial transactions and compensation paid to subjects and investigator/site for participating in the clinical trial shall be submitted.

National requirements and remarks:

The published template *Compensation for trial participants* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en.

Section 22, subsection 1 of the Act on Clinical Trials on Medicinal Products: “The costs for investigational medicinal products, auxiliary medicinal products, medical devices used for their administration and procedures specifically required by the protocol are free of charge to the participant unless there is a justified reason for charging for them”.

If there is a possibility that there might be some costs for the trial participant, the reason shall be explained. All equipment and products shall be specified and justified in the “other” section. Also, section 23 of the Act on Clinical Trials on Medicinal Products shall be followed.

71. Description of any other agreement between the sponsor and the site shall be submitted.

National requirements and remarks:

The agreement between the trial site and the investigator and/or the sponsor does not need to be included in the application. However, the ethics committee may request a supplement to the information already provided, if necessary.

Q. PROOF OF PAYMENT OF FEE

72. Proof of payment shall be submitted, if applicable.

This should be submitted in the “Form” section of the application.

National requirements and remarks:

See the instructions issued by the Finnish Medicines Agency (Fimea) on clinical trials, available at: https://fimea.fi/en/supervision/clinical_drug_trials.

R. PROOF THAT DATA WILL BE PROCESSED IN COMPLIANCE WITH UNION LAW ON DATA PROTECTION

73. A statement by the sponsor or his or her representative that data will be collected and processed in accordance with Directive 95/46/EEC shall be provided.

National requirements and remarks: No remarks.

STATEMENT OF THE COLLECTION, STORAGE AND FUTURE USE OF BIOLOGICAL SAMPLES

A statement on compliance with the applicable rules for the collection, storage and future use of biological samples of the subject, as set out in Article 7(1)(h) of the Clinical Trials Regulation.

National requirements and remarks:

The published template *Compliance with applicable rules for biological samples* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en.

With regard to the future use or long-term storage of samples, the statement must take into account the memorandum on sample collection in clinical trials (14.1.2022) by TUKIJA and Fimea, available at: https://tukija.fi/laaketutkimusasetuksen-mukaiset-hakemukset (in Finnish).

The document should be completed even if no biological samples are collected in the clinical trial. If no samples are taken, ”No” should be selected in section I, as well as in the other sections (provided that no biobank samples or other previously taken samples are used in the study). In this case, the numerical subsections (1.1–5.1) can be left blank or alternatively, NA (Not Applicable) can be marked in all sections.

PATIENT FACING DOCUMENTS (OTHER THAN RECRUITMENT MATERIALS OR PARTICIPANT INFORMATION SHEETS)

National requirements and remarks:

According to section 1.24 of the updated Q&A guidelines published by the EU Commission on 27th March 2026, any translations of forms intended for the research participant should be placed in Part II of the application. However, Tukija does not require the submission of translations separately in either part of the application. The patient facing documents (other than recruitment material or participation information sheets) shall be submitted in Part I of the application in Finnish, Swedish or English (generally in accordance with the language used in the protocol).

Questions and Answers Document - Regulation (EU) 536/2014:
https://health.ec.europa.eu/document/download/bd165522-8acf-433a-9ab1-d7dceae58112_en.

Contact information

National Committee on Medical Research Ethics (Tukija)

Visiting address: Ratapihantie 9, 00520 Helsinki
Postal address: P.O. Box 40, FI-13035 LVV
Telephone switchboard: +358 295 254 000
info@tukija.fi
www.tukija.fi