Tukija

Instructions
29.5.2026
T/446/2026

OPERATING PROCEDURES OF THE NATIONAL COMMITTEE ON MEDICAL RESEARCH ETHICS (Clinical Trials on Medicinal Products under the EU Clinical Trials Regulation 536/2014 and Biobank Activities)

1 Legal Framework for the Operation of the National Committee on Medical Research Ethics (Tukija)

National legislation is legally valid only in Finnish and Swedish; English translations are unofficial.

Act on Clinical Trials on Medicinal Products (983/2021)

Biobank Act (688/2012)

Government Decree on the Biobank Consent and Approval Document (983/2023)

Decree of the Ministry of Social Affairs and Health on Biobank Notifications (649/2013)

Act on the Medical Use of Human Organs, Tissues and Cells (101/2001)

Medical Devices Act (719/2021)

Decree of the Ministry of Social Affairs and Health on Fees Charged for Opinions Issued by the National Committee on Medical Research Ethics (145/2026)

Decree of the Ministry of Social Affairs and Health on Fees Charged for Clinical Trials on Medicinal Products (1235/2025)

Administrative Regulation 1/2022 of the Finnish Medicines Agency: Clinical Studies on Medical Devices

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014, on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/EC (Clinical Trials Regulation)

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC (MD Regulation)

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in Vitro Diagnostic Medical Devices and Repealing Directive 98/79/EC and Commission Decision 2010/227/EU (IVD Regulation)

The Finnish Government has appointed Tukija for the term of office from 31 January 2026 to 30 January 2030 (22 January 2026, VN/15544/2025; correction issued on 29 January 2026).

1.1 Meeting schedule

The Ethics Committee meets regularly, and meetings are held primarily on a weekly basis.

In accordance with the EU Clinical Trials Regulation, applications concerning clinical trials submitted via the EU portal and database (Clinical Trials Information System, CTIS), maintained by the European Medicines Agency (EMA), are subject to processing timelines defined in the Regulation.

2 Duties of Tukija

The duties of Tukija are specified by law. Its duties are:

- to issue opinions on clinical trials on medicinal products for human use and on modifications thereto (including combined pharmaceutical and medical device trials and clinical trials using biobank samples);
- to issue opinions on the establishment of and modifications to a biobank;
- to issue opinion on the medical use of human organs, tissues and cells when the aim is to use them in clinical trials;
- to serve as an expert on research ethics in clinical trials on medicinal products, to collaborate with the authorities and to promote public discussion on clinical trials.

Tukija is thus responsible for the ethical assessment of clinical trials on medicinal products. As of 31 January 2025, all clinical trial applications in the European Union (EU) and the European Economic Area (EEA) have been submitted via CTIS under the Clinical Trials Regulation.

The present operating procedures are valid for the procedure under the EU Clinical Trials Regulation. The Regulation distinguishes between ‘clinical study’, ‘clinical trial’ and ‘low-intervention clinical trial’.

In the case of applications for clinical trials under the Regulation that have been rejected by the Finnish Medicines Agency (Fimea), the applicant may request an administrative review in accordance with the Administrative Procedure Act (434/2003).

A decision issued on a request for administrative review may be appealed to an administrative court in accordance with the Administrative Judicial Procedure Act (808/2019). More detailed appeal instructions will be attached to the national authorisation decision.

The duties of Tukija also include issuing opinions on any plan to establish a biobank before it is entered in the national biobank register maintained by Fimea.

3 Application for a Clinical Trial

3.1 Processing of Applications

All applications for clinical trials under the Clinical Trials Regulation must be submitted in CTIS. The system is a centralised repository for data on clinical trials.

There is no need for a separate application for an opinion from Tukija, as Tukija will process the application in CTIS. Any requests for information, responses to those requests, and the national authorisation decision for a clinical trial shall be provided via CTIS. Sponsors of clinical trials who wish to obtain authorisation from the authorities for a clinical trial in one or more EU or EEA Member States shall only submit one application form and dossier of supporting material via CTIS for each clinical trial. Submitting an application form and dossier of supporting material for authorisation of a clinical trial also results in the clinical trial being publicly registered.

The application process and its timelines are laid out in the Regulation. Part I of the application shall be assessed by all the Member States Concerned (MSCs), coordinated by the Reporting Member State (RMS). Part II of any application involving Finland shall be assessed nationally by Tukija and Fimea.

The documents to be included in the application are specified in Annex I of the Regulation; the mandatory attachments are also listed in the course of the application process in CTIS. The European Commission has issued further instructions and form templates in respect of the documents specified in Annexes I and II. Further instructions on their use are provided on the Tukija website.

The national authorisation decision shall be made and appeal instructions issued by Fimea, and these shall be provided to the sponsor via CTIS.

A user must have an EMA (European Medicines Agency) account to use CTIS. If the user already has an EMA account, for instance in the EudraVigilance database or the substances, products, organisations and referentials (SPOR) database, no new account needs to be created. Users that do not have an EMA account may register via EMA's account management website at https://register.ema.europa.eu/identityiq/home.html.

Organisations may need to go through additional registration steps, depending on the level of user administration they select in CTIS. The organisation-based approach allows a single administrator to handle user administration at the organisation level (instead of administration of an individual study). This is intended for organisations that frequently submit clinical trial applications via CTIS. Organisations that opt for the organisation-based approach shall register in the EMA Organisation Management Service (OMS). They shall also register their senior administrator for CTIS via EMA Account Management.

In Finland, the national contact point as referred to in the Clinical Trials Regulation is Fimea: clinicaltrials@fimea.fi.

CTIS user support is available on the EMA website: https://euclinicaltrials.eu/support-info/.

The CTIS handbook for sponsors is available on the EMA website: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/clinical-trials-information-system-ctis-training-support.

Further information on the Clinical Trials Regulation is available on the European Commission website: https://ec.europa.eu/health/documents/eudralex/vol-10_en (Eudralex – Volume 10 – Clinical trials guidelines).

3.2 Processing of Clinical Trials at Tukija

Tukija members shall be provided with a meeting agenda, the relevant clinical trial application documents and other meeting documents mainly no later than one week before the Tukija meeting.

As a rule, all communication with the sponsor regarding the processing of the application shall be managed in CTIS. Opinions or minutes of the Ethics Committee meetings shall not be provided to sponsors. Requests for information (RFIs) shall be provided to sponsors via CTIS. Tukija opinions shall be provided to Fimea in accordance with the Act on Clinical Trials on Medicinal Products. The national authorisation decision shall be made by Fimea. The authorisation decision shall be issued within 50 days of receiving the validation notification in CTIS. If Requests for Information are sent out regarding the application, then the original period shall be extended, but by no more than 31 days. The clock on the authorisation decision does not stop for the duration of providing any responses to Requests for Information.

The period may be extended by 50 days in the case of an advanced therapy investigational medicinal product.

Tukija may also request an opinion from an external specialist on the study protocol.

Note that the time periods for responding to Requests for Information in both validation and review are also binding on the sponsor. If the time periods are not complied with, the application will lapse.

A fee shall be charged for clinical trials or modifications thereto in accordance with the Decree of the Ministry of Social Affairs and Health (1235/2025). Further information on fees is available from Fimea.

3.3 Substantial Modifications to Clinical Trials

All applications for modifications to clinical trials under the Clinical Trials Regulation must be submitted in CTIS. There is no need for a separate application for an opinion from Tukija,

as Tukija will process the application in CTIS. Any requests for information, responses to those requests, and the national authorisation decision shall be provided via CTIS.

The time periods are specified in the Regulation. The authorisation decision shall be issued within 43 days of receiving the validation notification in CTIS. If a substantial modification only applies to Part II of the application, the authorisation decision shall be issued within 38 days of the validation notification. If Requests for Information are sent out regarding the application, then the original period shall be extended, but by no more than 31 days. The clock on the authorisation decision does not stop for the duration of providing any responses to Requests for Information. The mandated attachments to a modification application are specified in Annex II of the Regulation, which lists the documents required for a substantial modification.

The national authorisation decision shall be made and appeal instructions issued by Fimea, and these shall be provided to the sponsor via CTIS.

Note that the time periods for responding to Requests for Information in both validation and review are also binding on the sponsor. If the time periods are not complied with, the application will lapse.

A fee shall be charged for clinical trials or modifications thereto in accordance with the Decree of the Ministry of Social Affairs and Health (1235/2025). Further information on fees is available from Fimea.

4 Application for an Opinion on the Establishment of a Biobank

4.1 Establishing a Biobank

A favourable opinion by Tukija is a precondition on the establishment of a biobank. Tukija must issue its opinion within 60 days of receiving a valid request for ethical evaluation. For its opinion, Tukija must determine whether the activities of the biobank meet the conditions concerning the protection of privacy and self-determination laid down in the Biobank Act and in other regulations and present a justifiable view on the ethics of the activities.

The following information and documents must be attached to the request for an opinion:

1. signed cover letter;
2. name or other identifier of biobank;
3. owner of biobank, business name of the owner and main financiers of biobank;
4. location and method of storing the samples and information associated with them and an account of arranging the management of information in the registers;
5. description of the biobank's area(s) of research and an account of the principles and terms to be applied in the collection, granting of access to for the purposes of

biobank research and other processing of samples and information associated with them and restrictions concerning the use of samples;

6. the consent form used and a model for a written report to be submitted when requesting consent or information on the content of the report and a description of submitting the report;
7. an account of whether samples and related information other than those based on consent will be stored in the biobank;
8. n account of whether samples and related information other than those owned by the biobank will be stored in the biobank and, if necessary, information on the owner of the samples;
9. an action plan that outlines the planned scale of the biobanking activities, the organisation of the activities and the division of responsibilities.
10. statement on the ethics of the activities of the biobank, especially the objectives and the planning of the biobank, as well as on the pre-evaluation of the risks and benefits of the biobank;
11. statement on the realization of the protection of privacy and self-determination of the donors.

The signed cover letter and attachments shall be submitted using the electronic application form for opinions available on Tukija's website at www.tukija.fi.

4.2 Changes to the Information Notified to the Biobank Register

Any substantial changes to the information provided to the national biobank register must be submitted to Tukija for ethical evaluation. Fimea shall assess the need for ethical evaluation. As a rule, changes must be submitted to Tukija if they relate to the information referred to in section 6 of the Biobank Act.

5 Fees

5.1 Clinical Trials under the Regulation

Fimea charges a fee for the processing of applications submitted via the EU portal and database in accordance with the Decree of the Ministry of Social Affairs and Health on Fees Charged for Clinical Trials on Medicinal Products (1235/2025). The fee charged by Fimea depends on the type of processing involved. Tukija does not charge a separate fee. Fimea provides guidance on matters related to invoicing and fee charging.

5.2 Applications for the Establishment of a Biobank and for Changes to Biobank Activities

Tukija charges a fee for the processing of applications concerning the establishment of a biobank and changes to biobank activities in accordance with the Decree of the Ministry of Social Affairs and Health on Fees Charged for Opinions Issued by the National Committee

on Medical Research Ethics (145/2026). The payment decision shall apply to all decisions requiring Tukija's consideration and opinion.

For the purpose of charging the fee, the application for an opinion shall include the invoicing address and the company's business ID.

Contact information

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Version history

Date	Description/Modification
11.2.2022	First version in Finnish.
5.4.2022	Ch. 3.4, Tukija's meeting frequency changed.
11.6.2025	Changes due to the end of the transition period for the Clinical Trials Regulation have been updated in the instructions.
3.10.2025	Minor edits to the content.
29.5.2026	A new decision on the appointment of the Ethics Committee has been added. In addition, minor corrections have been made: new decrees on fees, textual corrections, and updated Tukija contact information following the administrative reform. The formatting has been updated.