OPERATING PROCEDURES OF THE NATIONAL COMMITTEE ON MEDICAL RESEARCH ETHICS (clinical trials on medicinal products in accordance with the Directive 2001/20/EC)

1. Legal framework of Tukija's operations

Act on Clinical Trials on Medicinal Products (983/2021)
Medical Research Act (488/1999, with changes 295/2004, 794/2010, 143/2015 and 984/2021)
Government Decree on Medical Research (986/1999)
Government Decree on the Amendment of the 2 and 3 § of the Decree on Medical Research (313/2004, only in Finnish and Swedish)
Government Decree on the Amendment of the Decree on Medical Research (65/2016, only in Finnish and Swedish)
Decree of the Ministry of Social Affairs and Health on the Fees Charged for Opinions of the National Committee on Medical Research Ethics and Regional Ethics Committees (1171/2020, only in Finnish and Swedish)
Decree of the Ministry of Social Affairs and Health on Clinical Trials on Medicinal Products (841/2010)
Decree of the Ministry of Social Affairs and Health on the Compensation for Research Participation (82/2011)
Act of the Medical Use of Human Organs and Tissues (101/2001)
Medical Devices Act (719/2021)
Act on Certain Medical Devices Specified in EU Directives (629/2010)
Finnish Medicines Agency Fimea's Administrative Regulation (1/2022): Clinical Studies on Medical Devices
Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16th April 2014, on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Clinical Trials Regulation)

The formation of Tukija and the expertise of its members are stated in the Government Decision of appointment (27th January 2022, STM/2022/21; complemented on 8th July 2022, VN/32562/2021-STM-89).

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1.1 Meeting schedule

The Committee shall meet regularly, at least every other week. The meeting timetable shall be published on the Tukija website.

2. Duties of Tukija during the transition period

The present Operating Procedures are valid to substantial amendments for clinical trial applications (submitted via process described in the Directive 2001/20/EC) which are sent between 31st January 2023 and 30th January 2025 to Tukija or to a Regional Committee on Medical Research Ethics, whoever has reviewed the first application of the clinical trial.

Sponsors of clinical trials on medicinal products may submit substantial modifications for ongoing clinical trials in accordance with the procedure for submitting national applications under the Clinical Trials Directive (2001/20/EC). In case a clinical trial continues beyond January 2025, it should be transitioned into the EU portal and database (Clinical Trials Information System, CTIS) according to the Clinical Trials Regulation (536/2014). Ongoing clinical trials needs to be transferred on 31st January 2025 at the latest.

Clinical trials on medicinal products are interventional studies carried out on human subjects for the purpose of finding out the effects of drugs in humans and compiling information on the absorption, distribution, metabolism, and excretion of drugs in the human body (Finnish Medical Research Act, section 2 (6)).

Non-interventional trials are studies where the medicinal product(s) is (are) prescribed in a manner in accordance with the terms of the marketing authorization. The assignment of the patient to a specific therapeutic strategy is not decided in advance by a trial protocol but falls within the current medical practice, and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures are applied to the patients, and epidemiological methods are used for the analysis of collected data. (Directive 2001/20/EC, Article 2 (c).)

In the Directive-based process, opinions issued by Tukija cannot be appealed. However, Tukija can reconsider an application (as a new application) when changes introduced in the negative opinion have been made.

An application for Substantial Amendments (under the Directive-based process) that has previously been given a negative opinion by a Regional Committee on Medical Research Ethics (/Regional Ethics Committee) can be resubmitted unchanged, in which case the Regional Committee in question, when requested, is obligated to refer the case to Tukija and request its opinion.

The processes described above apply only to Substantial Amendments for clinical trial applications submitted before 31st January 2025.

3. Application for ethics review on Substantial Amendments for clinical trial on medicinal product(s)

3.1 Amendments to a clinical trial under the Directive 2001/20/EC (until 30.1.2025)

Tukija only reviews Substantial Amendments that are likely to have a bearing on the ethical aspects of the trial proposal. Substantial amendments include changes related, for example to the following issues:

- The physical or mental integrity of the trial subjects
- The scientific value and significance of the trial
- The implementation of trial protocol
- The quality or safety of investigational product

More detailed instructions on Substantial Amendments can be found in the guidelines published by the European Commission.

Applications for amendments are submitted to Tukija by using the application form issued by the Finnish Ministry of Social Affairs and Health completely filled. The application should be accompanied by a signed cover letter, a summary of the main contents of the updates/changes in Finnish, as well as the principal investigator's opinion on the ethicality of the trial, especially evaluation of the impacts of the changes/amendments on the ethics of the trial. With the exception of trial protocol and Investigator's Brochure (IB), all the documents should be in Finnish or Swedish.

An application should be submitted via electronic form that is available on Tukija's website (www.tukija.fi; the forms are available in Finnish and Swedish). If necessary, the application form as a PDF document (also found on Tukija's website) can be filled and sent by e-mail to hakemukset(at)tukija.fi.

Regarding the amendments introduced to the investigators' brochure, what is required from the investigator is a brief summary of the updates/changes, written in Finnish or Swedish, accompanied by the principal investigator's opinion on the effects of the proposed amendments. The opinion should include a statement on whether or not research participants need to be informed about the new safety-related information. In case the medicinal product has received MA during the ongoing trial, the updates of the investigators' brochure do not need to be submitted to Tukija. However, if the updates introduced to investigators' brochure call for amendments in other trial documents, such as the information presented to potential research subjects, then the application form must be submitted. The application needs to be accompanied by a signed cover letter, a summary of the main contents of the updates/changes in Finnish, as well as the principal investigator's opinion on the ethicality of the trial, especially evaluation of the impacts of the changes/amendments on the ethics of the trial.

Applicants can expect opinions on proposed amendments within 35 days of submitting admissible applications. The time required for obtaining any necessary additional information is not included when counting Tukija's deadline. A fee based on a decree issued by the Finnish Ministry of Social Affairs and Health is charged for processing a Substantial Amendments application.

In general, the opinions on the amendments to trial protocols are recorded to the minutes of the meeting, taking into account the secrecy regulations.

3.2 Transition of a clinical trial authorised under the Directive

If the sponsor considers that substantial modifications need to be done to the clinical trial to make it compliant with the Regulation and/or if the protocols of a clinical study employed in different countries are being harmonised to one protocol, these changes shall be made in the procedure specified in the Directive to Tukija. This is not dependent on which committee (TUKIJA/Tukija or a local ethics committee) has given favourable opinion for the clinical trial. After receiving a favourable opinion on the modification, the clinical trial shall be entered in the EU portal as a new clinical trial, using the simplified authorisation procedure. (Please see Commission Questions and Answers Document – Regulation (EU) 536/2014, Chapter 11 and CTFG Best Practice Guide for sponsors of multinational clinical trials with different protocol versions approved in different Member States under Directive 2001/20/EC that will transition to Regulation (EU) No. 536/2014.)

A fee of processing a Substantial Amendment application is charged according to the section 4.

3.3 Annual lists of serious adverse effects

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Sponsors are responsible for compiling lists of suspected cases of serious adverse effects identified in connection with trials each year for the relevant ethics committee. The lists must be accompanied by reports on safety of the trial subjects. The lists to Tukija together with a signed cover letter should be submitted via electronic form that is available on Tukija's website (www.tukija.fi the forms are available in Finnish and Swedish). If necessary, the application form as a PDF document (also found on Tukija's website) can be filled and sent by e-mail to hakemukset(at)tukija.fi.

If an annual list of adverse effects gives rise to suspicions that the safety of subjects has been compromised, Tukija can refer the matter to the Finnish Medicines Agency Fimea.

3.4 Notifications of termination

Sponsors or investigators must inform the relevant ethics committee of the completion of the clinical drug trial within 90 days. If a trial is discontinued prematurely, notification must be submitted within 15 days. The notification must specify the reasons for discontinuing the trial prematurely. Notifications of termination must be made using the application form issued by the Ministry of Social Affairs and Health.

Summaries of the findings of clinical trials on medicinal product(s) must be submitted to the relevant ethics committee within one year after completion of the trial.

The above-mentioned notifications and summaries to Tukija together with a signed cover letter should be submitted via electronic form that is available on Tukija's website (www.tukija.fi the forms are available in Finnish and Swedish). If necessary, the application form as a PDF document (also found on Tukija's website) can be filled and sent by e-mail to hakemukset(at)tukija.fi.

4. Fees

Fees for opinions imposed are based on the Decree of the Finnish Ministry of Social Affairs and Health. An Up-to-date decree can be found on Tukija's website in the section Legislation (https://www.tukija.fi/tukijan-toiminta/lainsaadanto).

If an applicant, a sponsor and/or an investigator wants Tukija to issue opinions on matters that Tukija would otherwise file as notifications, the subsequent fees can be based on the fees payable for amending trial protocols. No fees are charged for filing notifications.

Applicants/sponsors are requested to notify the invoicing address and Business Identity Code in applications.

5. Contact details

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National Supervisory Authority for Welfare and Health Valvira

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Applications and notifications, as well as responses to requests for additional information and for corrections (based on conditional positive opinions issued) should be submitted via electronic forms that are available on Tukija's website (www.tukija.fi the forms are available in Finnish and Swedish).

Version history

Date	Modification
11.2.2022	First version in Finnish.
5.4.2022	Ch. 3.4, Tukija's meeting frequency changed.
16.2.2023	Ch. 1 (a decree concerning an STM decree's validity added), ch. 3 (all the guidance related to a new clinical trial deleted; guidance on Substantial amendments revised; guidance on updating an IB complemented), ch. 4 (a reference to a valid decree on fees on Tukija's website added).
21.2.2023	Changes made accepted in Tukija's meeting.
13.3.2023	Language requirements added in the document; a technical change.