

23.1.2024 (unofficial translation 23.2.2024)

OPERATING PROCEDURES OF THE ADMINISTRATIVE REVIEW DIVISION

1. Legal framework of the Administrative Review Division

Medical Research Act (488/1999, unofficial translation)

Act on Electronic Services and Communication in the Public Sector (13/2003, unofficial translation)

Administrative Procedure Act (434/2003, unofficial translation)

Administrative Judicial Procedure Act (808/2019, unofficial translation)

1.1 Formation of the Administrative Review Division

The separate Administrative Review Division of the National Committee on Medical Research Ethics (Tukija) was appointed for the term 31 Jan 2022 – 31 Jan 2026 at the Government session on 27 Jan 2022 (STM/2022/21). The division shall have a chair and a deputy chair, and nine members and four deputy members. The division is a separate and independent executive body of Tukija.

1.2 Meeting schedule

The Administrative Review Division shall meet on an as-needed basis, once a month on predetermined dates.

2. Duties of the Administrative Review Division

The duties of the Administrative Review Division are to deal with requests for an administrative review in respect of rejection decisions (i.e. negative opinions) issued by Regional Committees on Medical Research Ethics according to the Medical Research Act (488/1999, section 3). The Division also processes the requests for an administrative review regarding the non-examination decision made by the Regional Committees.

The Administrative Review Division shall evaluate the medical studies (other than clinical trials on medicinal products) concerned as per the Medical Research Act. The division shall consider the application of the Medical Research Act on the basis of the request letter and ethics committee's statement or decision not to investigate, as well as the documents that were the basis of the negative decision.

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Under section 49 g of the Administrative Procedure Act when an authority has admitted for consideration a request for an administrative review, it may decide to amend the decision, rescind it (and return it to the Regional Committee on Medical Research Ethics for reconsideration), or reject the request for review. The decision on the request for an administrative review shall set out a reasoned response to the claims presented in the request.

3. Processing a request for an administrative review

Requests for an administrative review shall be submitted to the Administrative Review Division using the online form available on the Tukija's website. The cover letter shall identify the decision for which revision is being requested, the precise nature of the revision demanded and the grounds for demanding the said revision. The rejection decision issued by the Regional Committee on Medical Research Ethics and the material submitted to that Regional Committee, in full, shall be submitted to the division as attachments to the request for an administrative review.

The request for an administrative review shall be submitted to the Administrative Review Division within 30 days of receiving notice of the decision (opinion) of the Regional Committee. Requests for an administrative review not submitted within that time period shall not be processed.

The Administrative Review Division shall return an opinion as soon as possible t, but in any case, no later than four weeks after the meeting. In addition to the statement, the applicant is also provided with an extract from the minutes of the meeting. The statement with attachments is sent to the applicant as a standard notification. The statement can be sent as an electronic notification if the applicant has given his/her consent (Section 19 of Act on Electronic Services and Communication in the Public Sector).

The opinion shall also be sent to the Regional Committee for their information, as the statement given by the division is binding on it (Medical Research Act, Section 18 a). The Regional Committee shall continue to evaluate (substantial amendments of) the study in question after the Administrative Review Division has issued an approval decision on the medical study, on a modification thereto or on the resuming of the medical study after being suspended.

4. Appeal

An appeal can be filed against the statement issued by the division (administrative decision) by appealing to the regional administrative court in whose jurisdiction the appellant is domiciled (sections 8 and 10.3 of the Administrative Judicial Procedure Act).

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5. Fees

There is no fee for processing the request for an administrative review.

6. Contact information of the Administrative Review Division

Administrative Review Division, National Committee on Medical Research Ethics (Tukija)
National Supervisory Authority for Welfare and Health (Valvira)

Street address:

Ratapihantie 9
00520 Helsinki

Mail address:

PO Box 43, 00521 Helsinki, Finland
phone (switchboard): 0295 209 111

Further information: [info\(at\)tukija.fi](mailto:info(at)tukija.fi)

Requests for an administrative review are submitted via the Tukija's website: www.tukija.fi