

15.2.2022 (translation 2.5.2022)

## **OPERATING PROCEDURES OF THE ADMINISTRATIVE REVIEW DIVISION OF THE NATIONAL COMMITTEE ON MEDICAL RESEARCH ETHICS**

### 1. Legal framework of the Administrative Review Division

Medical Research Act (488/1999)

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

Administrative Procedure Act (434/2003)

#### 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 timetable

The Administrative Review Division shall meet on an as-needed basis, once a month on predetermined dates. Requests for an administrative review with its attachments shall be submitted no later than 14 days before a meeting date. The meeting dates shall be posted on the Tukija website.

### 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.

The Administrative Review Division shall evaluate the medical studies (other than clinical trials on medicinal products) concerned as per the Medical Research Act (488/1999, as amended). The division shall consider the application of the Medical Research Act in light of the request for an administrative review and of the rejection decision issued by the Regional Committee on Medical Research Ethics.

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Under section 49g 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 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 after their relevant meeting, but in any case, no later than one week after the meeting. The opinion of the division shall be sent to the party submitting the request for an administrative review, in electronic form. An extract from the minutes of the meeting detailing the matter shall be appended to the statement.

The opinion shall also be sent to the Regional Committee for their information. 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

### 5. Fees

No fee shall be collected for the processing of a request for an administrative review.

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## 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@tukija.fi)

Requests for an administrative review shall be submitted through the Tukija website: [www.tukija.fi](http://www.tukija.fi)