



Opinion Process of Regional Medical Research Ethics Committee

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5.3.2024

(unofficial translation)

Preparation and submission

- The applicant becomes familiar with the TETMK guidelines and templates
- The TETMK specialist and/or TETMK chairperson gives advice
- The applicant logs into eTutkija, makes an application for an opinion and attaches the annexes
- The TETMK secretariat and the specialist check and request any missing documents
- The applicant submits the missing documents and/or corrections within the agreed timeframe
- The working committee (TVK) examines the applications and selects the TETMK proposer

Processing

- The secretariat registers applications in the D10 system
- TETMK proposer prepare the presentations for the meeting
- TETMK meeting members discuss the application led by the proposer
- TETMK issues an opinion
- The secretariat draws up minutes and sends them to the proposer, the chairperson and examiner of minutes for checking
- The minutes are signed by the TETMK chairman, secretary and examiners
- The secretariat draws up extracts from the minutes (opinion) and sends the extract by e-mail to the applicant

**Opinion
(favourable /
negative / no
opinion)**

**Additional
clarification**

- The applicant replies to additional clarifications and posts them to eTutkija
- The TETMK meeting evaluates the response and issues an opinion
- The secretariat draws up the minutes
- The secretariat takes extracts from the minutes (opinion) and sends the extract to the applicant by e-mail

TETMK prosessi

Lyhenteet

TETMK = Regional Medical Research Committee

TETMK TVK = Working committee of Regional Medical Research Committee

Roolit / toimijat

Applicant = Principal Investigator / Sponsor / Contact Person

TETMK secretariat

TETMK specialist

TETMK chairperson

TETMK members of working committee (TVK)

TETMK proposer

TETMK meeting members

Preparation and submission of the request for an opinion

- The applicant becomes familiar with the TETMK guidelines and templates and liaise with the TETMK specialist and/or the TETMK chairperson if necessary
- The TETMK specialist and/or TETMK chairperson gives advice when requested
- The applicant logs into eTutkija, makes an application for an opinion and attaches the annexes
- The TETMK specialist will carry out a preliminary examination of the application (if the application has been received in time) and request any corrections from the applicant.
- The TETMK secretariat and the specialist check and request any missing documents
- The applicant submits the missing documents and/or corrections within the agreed timeframe

TETMK sub-committees and ja TETMK process

- The working committee (TVK) will process the applications and select the TETMK rapporteurs
- The secretariat enters the applications into the D10 system
- TETMK proposer prepare the presentations for the meeting
- TETMK meeting members discuss the application led by the proposer
- TETMK issues an opinion (favorable, request for additional clarifications, no opinion, negative opinion)
- Secretariat takes minutes of the TETMK meeting
- The secretariat sends the minutes of the TETMK meeting to the proposer, the chairperson and the examiner of minutes for checking
- The minutes are signed by the TETMK chairperson, secretary and the examiner of minutes
- The secretariat draws up the extracts from the minutes (opinion) and sends the extract by e-mail to the applicant

Additional clarifications

- The applicant makes responses (summary of modifications) to additional clarifications to requests for further evaluation and measures (amended items marked) and posts them to eTutkija.
- TETMK meeting evaluates the clarifications and issues an opinion
- The TETMK secretariat prepares an extract from the minutes (opinion) and sends the extract to the applicant by e-mail