

Regional Medical Research Ethics Committee of 5.3.2024
Wellbeing Services County of North Savo

Submitting Regional Medical Research Ethics committee's opinion application in eTutkija

(unofficial translation)

Logging in to eTutkija

Log in to eTutkija through the link omaKYS [Kirjaudu - Omakys](#). Logging into eTutkija is done using a secure card, mobile certificate, or online banking codes.

(Note; eTutkija is in Finnish only).

Submitting a new opinion application

On the eTutkija homepage, select "Alueellisen lääketieteellisen tutkimuseettisen toimikunnan lausuntohakemus" (*"Request for an opinion from the Regional Medical Research Ethics Committee"*).



Choose "Täytä uusi hakemus" (*"Fill in a new application"*).



After this, the eTutkija application form will open. Fill in the form with information of your research. Start by selecting the type of opinion application; this determines the documents to be attached to the application. Mandatory information is marked with an asterisk.

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Lausuntohakemuksen tyyppi *:

- Lausuntohakemus
- Lausuntohakemus näytteiden siirrosta biopankkiin ja käytöstä biopankkitutkimuksessa
- Lausuntohakemus biopankkitutkimuksesta

Lausuntohakemus (*Opinion Application*) = opinion application for new research (there is no previous opinion for the same research from the regional medical research ethics committee)

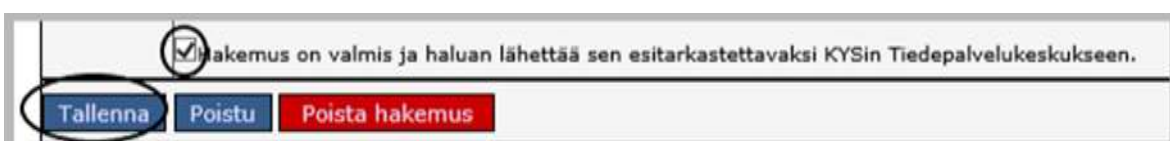
Lausuntohakemus näytteiden siirrosta biopankkiin ja käytöstä biopankkitutkimuksessa (*Opinion application for the transfer of samples to a biobank and their use in biobank research*) = opinion application for the transfer of previously collected samples to a biobank

Lausuntohakemus biopankkitutkimuksesta (*Opinion application for biobank research*) = opinion application for new research using samples and/or information in the biobank

The Medical Research Ethics Committee's opinion application form can be found on the committee's website, under [lausuntohakemuslomake](#) (*the opinion application form*) (in Finnish, word). On the website [Documents to be submitted - PSHVA - English - Pohjois-Savo \(pshyvinvointialue.fi\)](#), there are templates and instructions for filling out the opinion application. The Committee's templates include the required elements according to laws and guidelines. Attachments must be added in PDF format, and signed forms (e.g., opinion application form, ethical aspects evaluation) signed (e.g., scanned) as PDFs. Select the file from your computer and click "Liitä" (*Attach*). You can save the form by clicking the "Tallenna" (*Save*) button at the bottom of the form.



When the application is ready, and all necessary attachments have been added, check the box "Hakemus on valmis ja haluan lähettää sen..." (*The application is ready, and I want to submit it...*) and then click "Tallenna" (*Save*).



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After this, the application will appear in the listing under the Medical Research Ethics Committee's opinion applications tab.

Submission of Amendments, Notifications, Annual Reports, Additional clarifications requested by the Committee, and Supplements

Note: If you are submitting an amendment, notification, or annual report as your first application, meaning you have not previously submitted a research ethics committee opinion application through eTutkija, please inform the committee via email at tutkimuseettinentoimikunta@pshyvinvointialue.fi.

Log in to the eTutkija homepage and select "Alueellisen lääketieteellisen tutkimuseettisen toimikunnan lausuntohakemus" (*"Request for an opinion from the Regional Medical Research Ethics Committee"*).



A list of research on which you have the editing rights will be displayed. If the research you wish to modify is not visible, contact the Committee's specialist or secretaries, or email tutkimuseettinentoimikunta@pshyvinvointialue.fi.


Click on "Täytä muutokset, lisäselvitykset ja täydennykset" (*Fill out amendments, additional clarifications, and supplements*).

Täytä muutokset, lisäselvitykset ja täydennykset
Hakemus on valmis

Subsequently, the eTutkija application form will open. Fill in the form with information of your research. Start by selecting the type of opinion application; this determines the documents to be attached. Mandatory information is marked with an asterisk.

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Lausuntohakemuksen tyyppi *:

- Muutosilmoitus
- Lausuntohakemus tutkimuksen merkittävästä muutoksesta
- Ilmoitukset
- Vuosiraportit
- Lisäselvitykset 
- Täydennykset

Muutosilmoitus (*Amendment Notification*) = informal notification of minor changes to the research.

Lausuntohakemus tutkimuksen merkittävästä muutoksesta (*Opinion Application for a Significant Amendment to the Research*) = application for a change in the research that may affect the safety of research subjects, the physical and mental integrity of subjects, the scientific value and significance of the research plan, the implementation of the research plan, the quality or safety of the investigational product, or that alters the interpretation of scientific documents used to support the research. The research must not proceed according to the amended plan until the ethics committee has provided a positive opinion on the modified plan.

Ilmoitukset (*Notifications*) = matters reported to the committee that do not alter the conduct of the research. For example, notification of the end of the research, updated contact information, technical corrections, etc.

Vuosiraportit (*Annual Reports*) = an annual report of the safety of the research (a list of suspicions of serious adverse events in the research). A report on the safety of research subjects is required as an attachment to the annual report.

Lisäselvitykset (*Additional clarifications requested by the Committee*) = additional clarifications requested by the Committee regarding the research and its documents. In the clarifications, the principal researcher must provide responses to the requested additional information and summarize the changes made, attaching all modified documents. The changes must be clearly marked on the documents. Additional clarifications will be reconsidered at the committee's meeting.

Täydennykset (*Supplements*) = supplements are used when the documents of the application need to be corrected or additional documents need to be added after the submission deadline. Note: Supplements must be agreed upon in advance with the Committee's specialist or secretaries.

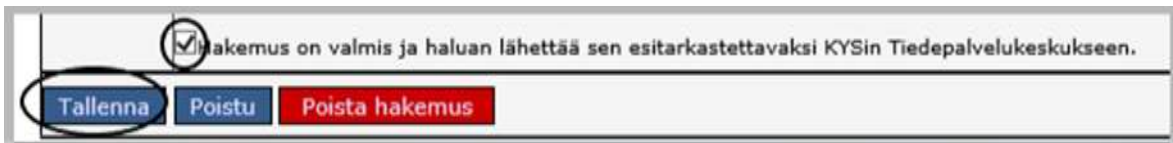
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The Medical Research Ethics Committee's opinion application form for a significant amendment can be found on the committee's website under [lausuntohakemus merkittävästä muutoksesta](#) (*The opinion application for a significant amendment*, in Finnish, word).

Attachments must be added in PDF format, and signed forms (e.g., opinion application form, cover letter, ethical aspects evaluation) signed (e.g., scanned) as PDFs. Select the file from your computer and click "Liitä" (*Attach*). You can save the form by clicking the "Tallenna" (*Save*) button at the bottom of the form.



When the application is ready, and all necessary attachments have been added, check the box " Hakemus on valmis ja haluan lähettää sen..." (*The application is ready, and I want to submit it...*) and then click "Tallenna" (*Save*).



After this, the application will appear in the listing under the Medical Ethics Committee's opinion applications tab for the respective research. The latest application will be at the top.