

Time 11 November 2015 13:02–15:43

Place Big Administration Meeting Room

Participants

	Name	Job	Time	Additional information
PRESENT	Aaltonen Leena-Maija	Chair	13:02–15:43	
	Järvinen Heikki	Member	13:02–15:43	
	Holopainen Juha	Member	14:09–15:43	Arrived during §223
	Raivio Peter	Member	13:02–15:04	Left after §231
	Leidenius, Marjut	Member	13:02–15:43	
	Cedercreutz Gabriella	Member, layperson	13:02–15:43	
	Svahnström Lasse	Member, layperson	13:02–15:43	
	Nikkinen Janne	Member, expert in ethical matters	13:02–15:43	
	Vento Jaana	Member	13:58	Arrived during §223
		Legal expert		
	Hember Micaela	Member	13:02–15:31	Left after §235
	Harju Mika	Substitute member	13:02–14:00	Left after §223
ABSENT	Keränen Ulla	Member		
	Koivusalo Anna-Maria	Member		
	Halme Leena	Member		
	Sainio Carita	Member		
	Marjamaa Johan	Member		
	Ilmakunnas Minna	Substitute Member		
	Tarkkanen Maija	Substitute Member		
	Rauta Satu	Substitute Member, repr. of nursing		
	Ritmala-Castrén Marita	Substitute Member, repr. of nursing		
	Suominen Sinikka	Substitute Member		
	Lehtonen Riitta	Substitute Member, layperson		
	Paavola Mika	Substitute Member		
	Matikainen Mika	Substitute Member		
	Kontio Risto	Substitute Member		
	Klockars Tuomas	Substitute Member		
OTHER	Ruuska Minna	Secretary	13:02–15:43	

364/13/03/02/15 NEW RESEARCH PLAN

364/13/03/02/2015

TMK02 §219

Publicity

Confidential Document (Resolution 621/1999, §24)

Name of Research

COMPARISON OF IMPLANTS AND TECHNIQUES USED IN NEW  
ACL-RECONSTRUCTION SURGERY, RESULTS OF 2–5 YEARS'  
FOLLOW-UP

Description

The Committee has been submitted a new research plan

The plan concerns medical research as part of the decree of Doctor of  
Medical Science, with the aim of judging, on the basis of a long-term  
follow-up of operated patients, the best/most successful fixation techniques  
of tendon grafts.

The timetable submitted to the Ethics Committee is 1 January 2016–31  
December 2021.

Person in charge of research

D.Med.Sc, docent Arsi Harilainen, Orton Hospital

Researchers

D.Med.Sc, docent Arsi Harilainen, Orton Hospital

D.Med.Sc, docent Jerker Sandelin, Orton Hospital

M.D. Ville Bister, HUS, Töölö Hospital

Lic.Med Leena Metso, HUS Töölö Hospital

Lic.Med Kirsi-Maaria Nyrhinen, HUS, Peijas Hospital

Lic.Med Arne Schlenzka, Central Hospital of Päijät-Häme

Commissioner of research

Research initiated by researcher

Financing of research

EVO-Financing of the Finnish Medical Association

Documents submitted

Application (form), 19 October 2015

Research plan

Abstract of research plan

Notice and consent document of research subject

Report of Personal Data Register, 19 November 2015

Curriculum Vitae Arsi Harilainen and Leena Metso

Decision proposal      The Ethics Committee shall decide  
1. On the matter in meeting proceedings  
2. To charge a statement fee of 0 euros (Decree of Ministry of Social Affairs and Health 1168/2014, Section 1, Paragraph 3)

Decision                      The Committee considers that the research plan and its appendices are in compliance with the stipulations of the Medical Research Act (488/99 with later amendments) and Medical Research Decree (986/99 with later amendments), data security regulations, as well as the international commitments concerning medical research and the position of research patients required from medical research of human beings.

The Ethics Committee considers the research plan ethically acceptable and decides

1. To give a statement in favour of the research plan, with the understanding that it is a retrospective document-based study where no contact is taken to patients.

2. To charge a statement fee as decided above.

The statement given by the ethics committee is not subject to appeal. If the decision of the ethics committee is negative, the commissioning party may resubmit the matter to the ethics committee unaltered. A regional ethics committee shall at the request of the commissioning party seek the opinion of the National Committee on Medical Research Ethics (Act on Medical Research 488/1999, with later amendments).

A party liable for payment who considers that an error has been committed in determining the fee may claim for rectification. Instructions for the rectification request are attached.

Further Information      Chairperson Leena-Maija Ahonen, GSM 050 427 1493  
Secretary of Committee Minna Ruuska, GSM 050 427 9345

The extract of the unexamined minutes is certified by

Helsinki, 17 November 2015

Minna Ruuska  
Secretary

Sent                              17 November 2015

Attachment

Instructions for lodging a rectification request

Distribution

Arsi Harilainen, Orton Hospital, Tenholantie 10, 00280 Helsinki  
Leena Metso, Töölö Hospital, P.O. Box 266

## RECTIFICATION REQUEST FOR DECISION ON STATEMENT FEE

**Right to claim for rectification**      Rectification for the statement fee on a research plan or its amendment set by an ethics committee may be claimed. A rectification request may be made by the person at whom the decision is directed or on whose right, obligation or benefit the decision has a direct effect (the party). Rectification for the decision of a joint municipal authority may also be claimed by a member municipality of the joint municipal authority or its member.

The rectification request shall be made in writing.

### Denial of rectification request

A rectification request may not be lodged on a decision concerning the preparation or execution of a decision, a decision made due to a rectification request, or a decision for which amendment is being applied on the basis of another Act.

The researcher or other party or a member municipality of a joint municipal authority or its member are not entitled to lodge a rectification request on a statement issued by the ethics committee. If the statement of the ethics committee is negative, the researcher may, however, submit the matter to the ethics committee again. The ethics committee is then liable to seek the opinion of the National Medical Research Ethics Committee.

### Authority for rectification requests

A rectification request on a decision concerning the fee for statement by an ethics committee shall be lodged addressed to the HUS Board.

### Time period of rectification request

The rectification request shall be made within 14 days on receipt of the decision. The decision is considered effected to the party, unless otherwise shown, within seven days of the dispatch of the letter, on the date of the advice of receipt, or on the date marked in a separate certificate of receipt. A member of the municipality is considered to have been served the decision, when the minutes have been displayed in public.

The date of the receipt of the decision is not counted in the period of the rectification request. If the last day of the rectification request is a Sunday or other such day when the office is closed for work, the rectification request may be submitted on the first weekday after that day.

## Contents of a rectification request

The rectification request shall state the following

- Name and domicile of applicant for rectification
- Home address and other contact information on where advice on the matter can be delivered
- Decision on which rectification is claimed
- Parts of the decision which are claimed for rectification, alterations demanded, and the grounds for the claim for rectification

The applicant for rectification or their legal representative or agent shall personally sign the rectification request. If the right to speak is exercised by someone other than the applicant for rectification personally, the rectification request shall also mention this person's name, domicile, postal address and other contact information through which advice on the matter can be delivered to the applicant for rectification.

## Delivery of rectification request

The party or the person authorised by the party shall submit the rectification request addressed to the HUS Board to the central registration office.

HUS keskuskirjaamo

P.O Box 200, 00029 HUS

(Visiting address: Tynnyrintekijänkatu 1 C, Helsinki)

Telephone: (09) 4711 (exchange)

Direct line: 050 428 7837 or 050 428 7838

Telefax: (09) 471 75500

Transactions by email: [keskuskirjaamo@hus.fi](mailto:keskuskirjaamo@hus.fi)

Customer service hours, weekdays 8 am to 3.30 pm.

The rectification request shall be submitted early enough for it to arrive by the last day before the closing time of the registration office of the hospital district. The rectification request may, at one's own risk, be sent by land mail, delivery service, fax or email.

A rectification request sent by email is considered delivered within the time limit, if it is available for the official's use in their reception device before the time limit has expired. If necessary, the applicant for rectification may be asked for the original signed copy of the rectification request sent by email, if there is reason to doubt the originality, integrity or unaltered form of the document (Act on Electronic Services and Communication in the Public Sector 13/2003).