



Applicant research entity

Stockholm County Council:

Investigator carrying out the project:

Henrik Falconer

Project title

Comparative multicentre study between robot-assisted laparoscopic surgery and open surgery in early cervical cancer

The Swedish Ethical Review Authority decides as follows.

DECISION

The Swedish Ethical Review Authority approves the research stated in the application subject to the following conditions:

1. The subject information sheet must be named research subject information sheet and not patient information sheet.
2. On the informed consent form, the penultimate point worded 'I give my approval for study-specific samples to be used for future research with relevance to the area of research following approval from the Swedish Ethical Review Authority' must be deleted. Any future use may take place only after a new application has been made to the Swedish Ethical Review Authority.

This decision may be appealed to the Ethics Review Appeals Board. The appeal procedure is described in the attached instructions.

On behalf of the Swedish Ethical Review Authority

Madelaine Tunudd
Chair



The following persons took part in the decision-making:

Chair

Madelaine Tunudd

Members with scientific expertise

Ulla Friberg (Otorhinolaryngology), Member

Anna Cristina Åberg (Geriatrics), Member

Torbjörn Karlsson (Anaesthesiology and intensive care), Member

Ann-Mari Bergström, Member

Anneli Stavreus-Evers (Gynaecology and reproductive medicine), Member

Jan Gustafsson (Paediatrics), Member

Jan-Erik Broman (Psychiatry), Member

Christer Sundström (Pathology), Scientific secretary

Elisabeth Ronne-Engström (Neurosurgery), Scientific secretary

Members representing general interests

Tommy Berger, Member

Inger Högström-Westerling, Member

Rolf Ahlzén, Member

Hannah-Karin Linck, Member

The decision is being sent to:

Principal investigator: Henrik Falconer

Representative of the research entity: Harald Blegen



How to appeal against the decision of the Swedish Ethical Review Authority

Who may appeal?

It is the research entity that may appeal against the decision of the Swedish Ethical Review Authority if it has gone against the applicant. The appeal must be in writing. The letter must be signed by an authorised representative of the research entity.

If the investigator appeals, a power of attorney from the research entity must be attached.

When must the appeal be lodged at the latest?

The appeal must have been received by the Administrative Court within three weeks from the date when the appellant was informed of the ruling.

What must the appeal contain?

The appeal must contain information on

1. the appellant's name, personal or corporate identity number, address, telephone number and e-mail address
2. the decision appealed against (date of decision, project title and reference number)
3. how you consider that the board's decision must be amended and the reasons why the decision should be amended.

Where must the appeal be sent?

The appeal is to be submitted to the Ethics Review Appeals Board. However, it is to be sent or handed over to the Swedish Ethical Review Authority.

If the appeal has been received in good time, the Swedish Ethical Review Authority will hand over the appeal and the documents to the Ethics Review Appeals Board.