

Ethical Review in Sweden

2020-14-21

Jörgen Svidén (ONEP)



Överklagandenämnden för etikprövning
ETHICS REVIEW APPEALS BOARD

Etikprövningslagen

Act concerning Ethical Review of
research concerning humans (2004)

Before: Voluntary committees (Universities)



Överklagandenämnden för etikprövning
ETHICS REVIEW APPEALS BOARD

Organisation

- Applications to the Swedish Ethical Review Authority
- Appeal to Ethics Review Appeals Board
- Governmental bodies



Överklagandenämnden för etikprövning
ETHICS REVIEW APPEALS BOARD

The Appeals Board

- 7 members – all with a substitute
- Chairman is a judge from the Supreme Court
- The Ethical Review Authority = 7 500 appl./year
- The Appeals Board = 50 – 100
- (Previously Research misconduct...)



Överklagandenämnden för etikprövning
ETHICS REVIEW APPEALS BOARD

Why an act?

- Protect human beings from physical harm
 - ...and integrity violence
 - Public control over ethical vetting
- Respect for human dignity in research



Överklagandenämnden för etikprövning
ETHICS REVIEW APPEALS BOARD

Reserach?

- Scientific experiment or theoretical work to obtain new knowledge on a scientific base...



Överklagandenämnden för etikprövning
ETHICS REVIEW APPEALS BOARD

Exception for student works

- Work that is performed as part of higher education at undergraduate or advanced level.
- However, works performed by students with the aim of publication in a scientific journal might still be approved...



3 §: What?

Research including

- sensitive personal data (race, ethnicity, political opinion, religion, trade union, health, sexuality)
- criminal sentences etc.



Överklagandenämnden för etikprovning
ETHICS REVIEW APPEALS BOARD

4 §: What...?

Physical or psychological harm

-physical intervention

-purpose of affecting a research person physically or mentally, or includes an apparent risk of injuring the research subject either physically or mentally

-studies of biological material that has been taken from a living person, and can be traced to that person

-physical intervention on a deceased person

-studies of biological material that has been taken from a deceased person for medical purposes, and can be traced to that person



Anyone can perform...

1 §

The purpose is to protect individuals



Överklagandenämnden för etikprövning
ETHICS REVIEW APPEALS BOARD

Where?

5 §

Applicable to research that is conducted
in Sweden

Approval - valid for 2 years



Överklagandenämnden för etikprövning
ETHICS REVIEW APPEALS BOARD

Information and consent

- Consent mandatory from participants -
IF physical intervention
- Consent - voluntary, expressed and
specified to certain research
 - Consent - documented
- Sensitive personal data - not mandatory



Benefits vs. risks



Överklagandenämnden för etikprövning
ETHICS REVIEW APPEALS BOARD

Supervision

- New task for the Board 1 January 2020
- ✓ Approved research: is the study within the approval? (Main task)
- ✓ Research without approval: mainly by reports
- ✓ Fine or imprisonment – 2 years



An example...

- The Public Health Agency of Sweden recently tested some 10 000 students and employees for Corona
 - Aim to perform research
 - Scientifically skilled person leading the study
 - Use of scientific methods
 - Aim to publish the result = research!
 - Questions regarding health = sensitive personal data + intervention (blood samples)
 - = needed ethical permission. Had they?

