Author's response to reviews

Title: Asthma and COPD in primary health care, quality according to national guidelines: a cross-sectional and a retrospective study.

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Author's response to reviews: see over
To the Editor, BMC Family Practice,

We hereby submit our revised version of the manuscript “Asthma and COPD in primary health care, quality according to national guidelines: a cross-sectional and a retrospective study”.

According to Swedish law no ethical approval is required for this kind of study, since it includes no personal data. This is now clearly stated in the manuscript (page 6). See below the full reference from the Swedish ethical vetting committee, available at http://www.epn.se/start/background-and-regulations/the-ethical-review-act.aspx.

The Act concerning the Ethical Review of Research Involving Humans

SFS number: 2003:460
Ministry/authority: The Ministry of Education and Cultural Affairs
Heading: The Act concerning the Ethical Review of Research Involving Humans (2003:460)
Issued: 5 June 2003
Changes made: up to and including SFS 2004:198

Section 1

This statute contains regulations concerning the ethical vetting of research concerning humans and biological material from humans. It also contains regulations concerning consent to such research.

The purpose of the act is to protect individuals and human dignity when research is conducted.

Definitions

Section 2

In this statute “research” refers to:
scientific research and development work on a scientific basis;
“responsible research body” refers to a government authority or a physical or legal entity under whose auspices the research is conducted and
“research subject” refers to a living person who is the subject of the research.

Applicability

Research that is subject to the statute

Section 3
This statute is applicable to research that involves dealing with
1. sensitive personal data as defined by section 13 of the Personal Data Act (1998:204), or
2. personal data concerning offences against the law that include crimes, judgements in criminal cases, coercive
   penal procedural measures or administrative deprivation of liberty as defined in section 21 of the Personal Data
   Act
if the person who is the subject of the research has not expressly consented to this.

Section 4

In addition to the consequences of section 3, this statute is to be applicable to research that
1. involves a physical intervention affecting a person who is participating in the research,
2. is conducted in accordance with a method intended to physically or mentally influence a person who is
   participating in the research,
3. concerns studies of biological material that has been taken from a living person and that can be traced
   back to that person,
4. involves a physical intervention upon a deceased person, or
5. concerns studies of biological material that has been taken for medical purposes from a deceased
   person and can be traced back to that person.

Yours sincerely

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