



## Letter concerning Swedish ethics review-system

The institutional review of research with human participants in Sweden is mainly regulated by the Ethics Review Act (2003:460). According to that law, an institutional review is performed by a national agency (the Ethics Review Authority) and is legally required for any scientific or scholarly research activity (1) performed in Sweden that (2) fulfills at least one of the following criteria:

- there is a physical intervention upon the research person (alive or deceased)
- the research method is intended to physically or psychologically affect the research person
- there is an obvious risk of physical or psychological harm
- biological matter from the research persons (alive or deceased) is used and traceable to them
- sensitive personal data or personal data concerning the crime record are handled.

‘Sensitive personal data’ is legally defined by the General Data Protection Regulation (EU) article 9.1 as data that can be traced to a single, identifiable individual and concerns ethnic background, political opinions, religious or philosophical convictions, union membership, health, sexual habits or orientation, genetical or biometrical data.

Exempted from the scope of the act is work for first and second-cycle studies (unless published in scientific channels) and any activities outside Sweden.

The Ethics Review Authority distributes applications for ethics review to ethics committees consisting of researchers and public representatives, which may approve, approve with requirements, deny or dismiss applications.

In cases where those criteria are not fulfilled, a legally valid ethics review is not required. As a service, however, the Ethics Review Authority offers an advisory opinion in such cases. Also, Swedish universities are obligated to support their staff on research integrity and research ethics.

The KTH’s Ethics Committee (of the Faculty Council) may provide an advisory opinion on certain projects that may be research-ethically controversial but do not fulfill any of the above criteria. The application procedure is less demanding than applying for an opinion from the Ethics Review Authority. The KTH’s Ethics Committee provides opinions on projects only before they commence.

The KTH ethics advisor at the Research Support Office primarily offers support on legal requirements.

While, traditionally, the Swedish ethics review system relies on trust in the researcher’s ethics competence, the research ethics of most projects that do not fulfill the above-listed criteria are handled internally by the group performing the research.

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