



UPPSALA
UNIVERSITET

Reg. No. JURFAK 2018/55

Guidelines for applying for ethical review

Faculty of Law

Adopted by the Faculty Board of Law 31 August 2018
Revised 18 February 2021 (*Translation provided for
information only. In all matters of interpretation, the
Swedish original document takes precedence.*)

Guidelines at the Faculty of Law

- Research at the Faculty of Law must be conducted in accordance with *lag (2003:460) om etikprövning av forskning som avser människor* (Act concerning the Ethical Review of Research involving Humans, short name the Ethical Review Act) and the precedents of the Ethics Review Appeals Board (ÖNEP, formerly the Central Ethical Review Board – CEPN).
- All researchers who are planning to conduct research at the Faculty of Law are required to make an assessment of whether or not the research is subject to ethical review.
- Applications for ethical review must be submitted before research involving the processing of sensitive personal data is initiated.
- If there is uncertainty surrounding whether the planned research requires ethical review, the responsible researcher must contact the Research Committee.
- The principal supervisor is responsible for doctoral projects being submitted for ethical review under the Ethics Review Act and the precedents developed by CEPN and ÖNEP.
- In the case of doctoral projects, the application for ethical review must be submitted after admission to the doctoral programme but before the start of the research project.
- If a doctoral student changes the principal supervisor for a project that has passed ethical review, an amendment application must be submitted to the Swedish Ethical Review Authority.
- The costs of applying for ethical review for research carried out by permanent staff and doctoral students are borne by the Department of Law, or another research funder.
- Costs for ethical review should be included in the budget when applying for external research funding.

Research requiring ethical review under the Act concerning the Ethical Review of Research involving Humans

Under the Ethical Review Act, *research* involving *the processing of sensitive personal data*, i.e. racial or ethnic origin, political views, religious or philosophical beliefs, trade union membership, health and sex life, or personal data relating to violations of the law involving criminal offences, criminal convictions, criminal prosecution, coercive measures or administrative detention may only be carried out if it has passed ethical review (Section 6 Ethical Review Act).

According to the Ethical Review Act “*research*” means scientific experimental or theoretical work or scientific studies by observation, if the work or studies are carried out in order to acquire new knowledge; and development work on a scientific basis, but not work or studies carried out solely within the context of higher education at first- or second-cycle levels (Section 2 second paragraph Ethical Review Act). Both basic research and experimental research are included. According to the travaux préparatoires, a *scientific* approach means that “the work is to be part of a knowledge process in which knowledge is systematised and structured through theory development and the application of methodological tools”.¹ If the study will be published in a scholarly context or form part of a thesis, it constitutes research as defined in the Act and interpreted by CEPN and ÖNEP.

Processing of personal data means the processing referred to in Article 4(2) of the General Data Protection Regulation (GDPR, EU 2016/679) (Section 2 fifth paragraph Ethical Review Act)² i.e. any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

An application for ethical review is to be submitted by the *research principal* (Section 3 Ethical Review Act). The research principal is Uppsala University, which in this case is represented by the Head of the Department of Law.

Decisions denying approval may be appealed by the research principal to the Ethics Review Appeals Board (ÖNEP).

¹ Govt. Bill 2007/08:44 page 51.

² Previous Section 3 of the Personal Data Act (1998:204). PUL was repealed on 25 May 2018. See instead the definition of processing in Articles 4(2), 9 and 10 of the GDPR. See also Govt. Bill 2007/08:44 page 51.

A person who intentionally breaches Section 6 first or second paragraph of the Ethical Review Act may be sentenced to a fine or imprisonment for a maximum of two years (Section 38 paragraph 1 Ethical Review Act). If the offence is commissioned as a result of gross negligence, the sentence shall be a fine or a maximum term of imprisonment of six months (Section 38 paragraph 2 Ethical Review Act).³

Guidelines on how to prepare an application, forms, etc., are available on the Swedish Ethical Review Authority's website, <https://etikprovningmyndigheten.se/> and on the ÖNEP website, <https://www.onep.se/start/>

On legal research and ethical review

According to CEPN's (now ÖNEP's) precedents, the Ethical Review Act is applicable to legal research.

Legal research that falls within the scope of the Ethical Review Act requires ethical review and must be subject to ethical review. The question of whether traditional legal research applying a legal dogmatic research method that is based mainly on public material is covered by the Ethical Review Act has been given great attention in the scholarly community.⁴ The question is under investigation. A number of authors have pointed out that requiring ethical review of legal dogmatic research may be unconstitutional. An assessment must be made in the individual case.

In two precedents, the former appeals body CEPN took a position on whether legal dogmatic research based on investigations of cases is subject to ethical review.

In the first case⁵ the cases would be retrieved from Infotorg. The judgments would be read directly on the screen and not saved to a hard drive. Quotes from the judges would be reported with reference to the case number. The applicant argued that traditional legal dogmatic analysis of the reasons for the judgment in criminal cases falls outside the Ethical Review Act with reference to the principle of public access to official records. In its decision, CEPN made a distinction between access to public documents and the use of information from public documents in research. The CEPN argued that the Ethics Review Act does not limit the right to study public documents. In addition, CEPN found that quotes from judgments together with the case number constitutes the processing of personal data and that therefore the Ethics Review Act is applicable.

³ See Uppsala University Guidelines (UFV 2019/1612) regarding failure to comply with accepted recommendations for obtaining authorisation from the relevant authorities.

⁴ For example, see V. Persson, Grundlagsstridigt krav på etikprovning?, FT 2015 pp. 603–627; the same Etikprovning av rättsvetenskap, in Festskrift till Wiweka Warnling Conradsson, Stockholm 2019 pp. 317–332; I. Cameron, Etikprovning av rättsdogmatisk forskning, FT 2019 pp. 31–47.

⁵ Reg. No. Ö 14-2015.

The second case⁶ dealt with research in medical law. The purpose of the research was to clarify the meaning of the term “science and proven experience” in order to develop a model for the judicial assessment of medical evidence. The application was for the analysis of judgments (including precedents) and other decisions by authorities. The application concerned public material only. The applicant argued that forensic analysis of judgments of precedents and published decisions of the highest instance cannot be deemed subject to ethical review even if sensitive personal data appear in the decisions being treated. CEPN found that the analysis was subject to ethical review in its entirety.

⁶ Reg. No. Ö 30-2015.